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14. ABSTRACT

The Prevention of Low Back Pain in the Military (POLM) clinical trial has been successfully completed. With the no cost extension year the research team completed all remaining SOW tasks with particular attention paid to the primary data analyses. In the no cost extension year the research team presented data at a national physical therapy conference and 2 manuscripts were accepted for publication in J Ultrasound Med BMC and Musculoskelet Disord. Our primary analyses suggest that the core stabilization exercise approach did not have preventative effects for low back pain. However, the brief psychosocial education approach did have preventative effects by resulting in a 3.3% decrease in low back pain incidence over 2 years (NNT = 30). The analyses for incidence outcomes are in review with Archives Int Med and for severity outcomes with Pain. The completion of the POLM trial provides important evidence that Soldiers may benefit from patient education approaches to reduce incidence of low back pain.

15. SUBJECT TERMS
Primary prevention; cluster randomized trial; low back pain; core stabilization; biopsychosocial;

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INTRODUCTION

Low back pain (LBP) is a musculoskeletal condition that accounts for significant pain and disability, and consumes substantial medical and occupational costs annually. Specific to the United States Armed Forces, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually (MSMR 2003). Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury. Furthermore, a military review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Therefore, reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs.[2] Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur.[1] Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. We are proposing an innovative approach to LBP prevention by combining primary and secondary prevention strategies that have the potential to limit the development of chronic LBP in Soldiers.

Objective/Hypothesis
The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combined prevention program is more effective at limiting the development of chronic LBP when compared to the effects of individual evidence-based prevention programs, or a traditional exercise program.

Specific Aims
Specific Aim 1: We will determine if a combined prevention program consisting of core stabilization exercise program (CSEP) and psychosocial educational program (PSEP) prevents the development of chronic LBP. During advanced individual training (AIT), United States Army Soldiers who volunteer will be randomly assigned to receive 1 of 4 prevention programs. Soldiers will be followed monthly during the first 2 years following AIT to measure LBP occurrence and severity with a web-based data collection system managed at the University of Florida.

Specific Aim 2: We will determine if the CSEP results in favorable changes in specific core musculature associated with reducing LBP. The CSEP activates specific core musculature that is important in preventing LBP. We will use real-time ultrasound imaging to measure changes in core musculature that occur during AIT. We will also determine if the PSEP results in a favorable change in LBP beliefs. The PSEP educates individuals in an evidence-based, psychosocial approach to the management of LBP, which can potentially decrease the likelihood of experiencing chronic LBP. We will use a validated self-report questionnaire to measure Soldiers' LBP beliefs regarding outcome and management. We will measure LBP beliefs at the beginning and end of AIT (a 12-week period).

Relevance: The results of this study will have several immediate applications for Soldiers. The widespread incorporation of effective preventative strategies will certainly result in a substantial reduction of LBP in the military. Programs that effectively prevent the occurrence and severity of LBP would benefit the U.S. Armed Forces by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers. For example, an average

cost of $136.02 per LBP visit was calculated for 2004. A 40% reduction in the recurrence of LBP after completing the CSEP would generate a cost savings of $3,343,230 by the 4th fiscal year (approximately 1/5 of the total cost of LBP for one FY).

Low back pain prevention programs are necessary to reduce the impact of musculoskeletal injury in the United States Military. Low back injuries are a significant cause of disability in the United States Army. For example in the United States Military, LBP was the second most common reason to seek healthcare and affected over 150,000 active duty Soldiers. Soldiers in the United States Army with LBP have the highest risk of disability 5 years after injury and a review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Clearly, quality clinical research producing evidence related to LBP prevention is warranted for the United States Military.

Programs that effectively prevent the occurrence and severity of LBP would benefit the United States Military by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers.

BODY

Specific tasks completed during the no cost extension:

Task 4: Dissemination of research findings
- Analyze and report pre-training findings
    - Scientific meeting (poster or platform presentation)
    - Manuscript submission
- Analyze and report post-training findings (Specific Aim #2 and #3)
    - Scientific meeting (poster or platform presentation)
    - Manuscript submission
- Analyze and report final findings (Specific Aim #1 and #3)
    - Scientific meeting (poster or platform presentation)
    - Manuscript submission

The following recurring Tasks occurred during the no cost extension:

Task 5: Complete quarterly procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per quarter**)
- Conference call between all investigators
- Prepare quarterly reports
    - Manual of Operations
    - Monitor human subjects and safety monitoring

Task 6: Complete annual procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per year**)
- On-site meeting between principal investigators
- Prepare annual reports
    - Manual of Operations
    - Human subjects and safety monitoring
- Renew institutional human subjects approval

Task 7: Prepare future proposals (Year 4)
- Conference call to discuss future DOD proposals related to prevention/treatment of musculoskeletal pain
    - Utilize established study infrastructure for data collection and management
    - Maintain established investigative team
- Preparation of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain
- Submission of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain

During the no cost extension year the statistical team completed all post training analyses and currently the papers are in press at *BMC Medicine* (incidence data) and *PLoS One* (self-report data).   Copies of these papers are included in the appendix.

KEY RESEARCH ACCOMPLISHMENTS

- Decreased LBP incidence observed in response to the psychosocial education program (PSEP) as described in the below Figures.

- Baseline predictors of first episode of low back pain identified for Soldiers training to be combat medics.
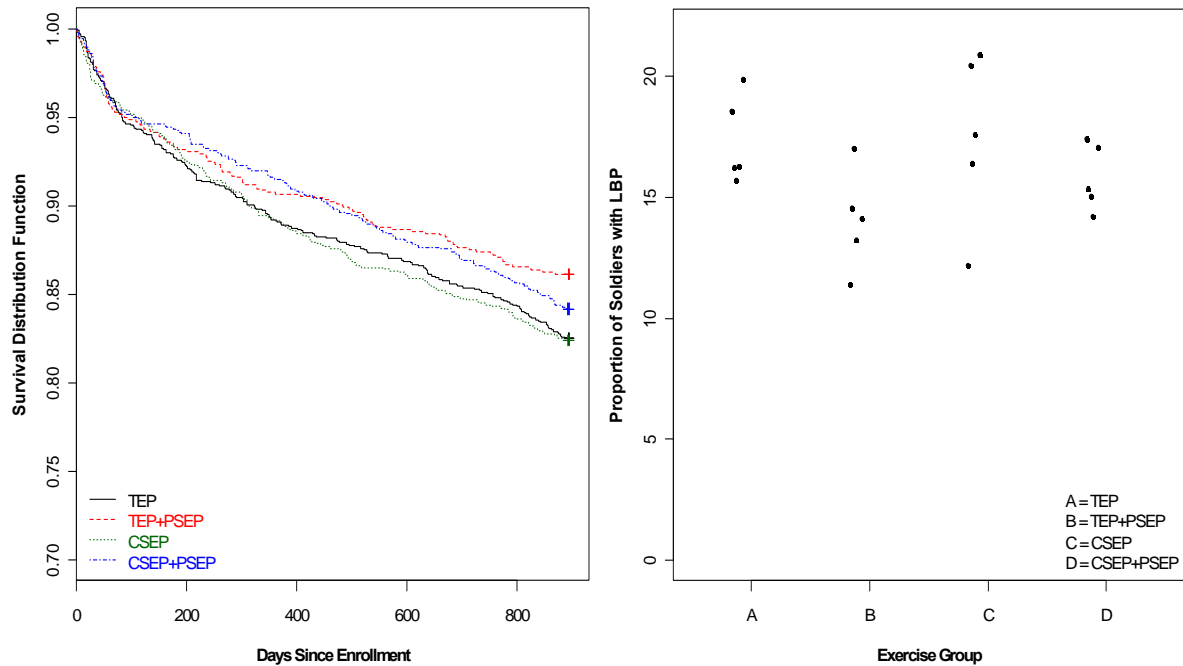
REPORTABLE OUTCOMES

<u>Peer-Review Publications (Attached in Appendix)</u>

1. George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Brief psychosocial education, not core stabilization, reduced health care utilization for low back pain: results from the Prevention of Low Back Pain in the Military (POLM) cluster randomized trial. *BMC Medicine*, 2011;9:128.
2. Childs JD, Teyhen DS, Van Wyngaarden JJ, Dougherty BF, Ladislas BJ, Helton GL, Robinson ME, Wu SS, George SZ. Predictors of web-based follow-up response in the Prevention of Low Back Pain in the Military Trial. *BMC Musculoskelet Disord*, 2011;12:132.
3. Teyhen DS, George SZ, Dugan JL, Williamson JN, Neilson BD, Childs JD. Inter-rater reliability of ultrasound imaging of the trunk musculature among novice raters. *J Ultrasound Med,* 2011;30(3):347-356.
4. Childs JD, Teyhen DS, Casey PR, McCoy-Singh KA, Feldtmann AW, Wright AC, Dugan JL, Wu SS, George SZ. Effects of traditional sit-up training versus core stabilization exercises on short-term musculoskeletal injury rates in US Army Soldiers: A randomized clinical trial. *Phys Ther*, 2010;90(10):1404-1412.
5. Childs JD, Teyhen DS, Benedict TM, Morris JB, Fortenberry AD, McQueen RM, Preston JB, Wright AC, Dugan JL, George SZ. Effects of sit-up training versus core stabilization exercises on sit-up performance. *Med Sci Sports Exerc*, 2009;41(11):2072-2083*.*
6. George SZ, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Robinson ME, Childs JD. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting. *Eur Spine J*, 2009 18(7):1050-1058.
7. Robinson ME, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Childs JD, George SZ. Mental health symptoms in combat medic training: a longitudinal examination. *Mil Med*, 2009;174(6):572- 577.
8. George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009). *BMC Musculoskelet Disord,* 2007;8:92.

<u>Abstracts (Attached in Appendix)</u>

1. Childs J, Wu S, Van Wyngaarden J, Dougherty B, Ladislas B, Helton G, Teyhen D, George S. Predictors of web-bsed response rate in the Prevention of Low Back Pain in the Military trial. *J Orthop Sports Phys Ther,* abstracted 2011.
2. Childs JD, Teyhen DS, Wright AC, Dugan JL, Casey P, McCoy-Singh K, Weston A, George SZ. The effects of traditional sit-up training versus core stabilization exercises on musculoskeletal injury rates in US Army Soldiers: a cluster randomized trial (NCT00373009). *J Orthop Sports Phys Ther,* abstracted 2010.
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5. Teyhen, DS, Childs JD, Hall NM, Gervacio SC, Lopez JA, Mitchler JR, Wright A, Dugan JL, George SZ. The influence of sex, height, and weight on trunk muscle thickness and endurance. *J Orthop Sports Phys Ther,* abstracted 2009.
6. George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, and Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (polm) trial (NCT00373009). *Proceedings of the 10th Annual Force Health Protection Conference*, abstracted 2007.

CONCLUSION

The POLM research team was able to complete all SOW tasks in a timely fashion with one year of the no cost extension to allow for completion of primary analyses and dissemination. We were able to recruit a cohort of 4,325 Soldiers, cluster randomize whether they received core stabilization and/or brief psychosocial education, and then determine whether low back pain episodes were reduced over the next 2 years. We overcame the challenge of low follow up rates with our original planned self-report tool by acquiring health care utilization data for low back pain. Final analysis provided an answer for our primary study question, and even though it was counter to our original hypothesis the finding that psychosocial education can potentially decrease low back pain incidence is an important finding. This education program could easily be implemented in different settings to determine if it provides Soldiers with better coping strategies in response to musculoskeletal pain, which in turn could reduce the burden and medical evacuation associated with musculoskeletal pain. The POLM trial was very productive from a peer-review publication perspective, as 8 were included with this final report. Overall data from the POLM trial also generated 6 published abstracts and we anticipate 2-3 additional papers related to the ultrasound imaging analysis of the trunk muscles and a cost effectiveness analysis of the primary outcome. Most importantly the data from this trial provide encouraging direction for future studies geared at preventing musculoskeletal pain.

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APPENDICES

1. Pages 12 – 43: George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Brief psychosocial education, not core stabilization, reduced health care utilization for low back pain: results from the Prevention of Low Back Pain in the Military (POLM) cluster randomized trial. *BMC Medicine*, 2011;9:128.

2. Pages 44 – 54: Childs JD, Teyhen DS, Van Wyngaarden JJ, Dougherty BF, Ladislas BJ, Helton GL, Robinson ME, Wu SS, George SZ. Predictors of web-based follow-up response in the Prevention of Low Back Pain in the Military Trial. *BMC Musculoskelet Disord*, 2011;12:132.

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6. Pages 86 – 94: George SZ, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Robinson ME, Childs JD. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting. *Eur Spine J*, 2009 18(7):1050-1058.

7. Pages 95 – 100: Robinson ME, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Childs JD, George SZ. Mental health symptoms in combat medic training: a longitudinal examination. *Mil Med*, 2009;174(6):572- 577.

8. Pages 101 – 111: George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009). *BMC Musculoskelet Disord,* 2007;8:92.

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14. Page 124: George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, and Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009). *Proceedings of the 10th Annual Force Health Protection Conference*, abstracted 2007.

BMC Medicine

Brief psychosocial education, not core stabilization, reduced incidence of low back pain: results from the Prevention of Low Back Pain in the Military (POLM) cluster randomized trial

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Brief psychosocial education, not core stabilization, reduced incidence of low back pain: results from the Prevention of Low Back Pain in the Military (POLM) cluster randomized trial

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Abstract

Background: Effective strategies for the primary prevention of low back pain (LBP) remain elusive with few large-scale clinical trials investigating exercise and education approaches. The purpose of this trial was to determine whether core stabilization alone or in combination with psychosocial education prevented incidence of low back pain in comparison to traditional lumbar exercise.

Methods: The Prevention of Low Back Pain in the Military study was a cluster randomized clinical study with four intervention arms and a two-year follow-up. Participants were recruited from a military training setting from 2007 to 2008. Soldiers in 20 consecutive companies were considered for eligibility (n = 7,616). Of those, 1,741 were ineligible and 1,550 were eligible but refused participation. For the 4,325 soldiers enrolled with no previous history of LBP average age was 22.0 years (SD = 4.2) and there were 3,082 males (71.3%). Companies were randomly assigned to receive traditional lumbar exercise, traditional lumbar exercise with psychosocial education, core stabilization exercise, or core stabilization with psychosocial education, The psychosocial education session occurred during one session and the exercise programs

were done daily for 5 minutes over 12 weeks. The primary outcome for this trial was incidence of low back pain resulting in the seeking of health care.

Results: There were no adverse events reported. Evaluable patient analysis (4,147/4,325 provided data) indicated no differences in low back incidence resulting in the seeking of health care between those receiving the traditional exercise and core stabilization exercise programs. However, brief psychosocial education prevented low back pain episodes regardless of the assigned exercise approach, resulting in a 3.3% (95% CI: 1.1 to 5.5%) decrease over two years (numbers needed to treat (NNT) = 30.3, 95% CI = 18.2 to 90.9).

Conclusions: Core stabilization has been advocated as preventative, but offered no such benefit when compared to traditional lumbar exercise in this trial. Instead, a brief psychosocial education program that reduced fear and threat of low back pain decreased incidence of low back pain resulting in the seeking of health care. Since this trial was conducted in a military setting, future studies are necessary to determine if these findings can be translated into civilian populations.

Trial Registration: NCT00373009 at ClinicalTrials.gov - http://clinicaltrials.gov/

{Key Words: primary prevention; core stabilization; patient education; incidence; low back pain}

Background

Musculoskeletal pain, and especially low back pain (LBP), adversely affects military preparedness as common reasons for medical evacuation [1] with return to duty being uncertain [1, 2]. Furthermore, LBP is also a common reason for long-term soldier disability [3]. It is not surprising then that prevention of LBP remains a high research priority for the general [4] and military societies [1, 2].

Effective strategies for preventing LBP remain elusive. Physical exercise has consistent evidence for primary prevention of LBP compared to no activity [5], but a review for the European Guidelines for Prevention of Low Back Pain indicated there were not enough studies to allow for recommendations differentiating types of exercise [6]. Back schools, lumbar supports and ergonomic interventions have limited support in systematic reviews [5, 7], and, therefore, are not recommended for primary prevention of LBP [6]. Education for primary prevention of LBP has received mixed support in trials [5]; there has been some support for psychosocial education, but not for biomedical or biomechanical based education programs [6]. Priorities for LBP prevention research noted in the European Guidelines included higher quality randomized trials that investigated specific physical exercise interventions in combination with psychosocial education [6].

The Prevention of Low Back Pain in the Military (POLM) cluster randomized clinical trial incorporated core stabilization exercise because of its preventative potential [8, 9]. We also incorporated psychosocial education based on the Fear-Avoidance Model of Musculoskeletal Pain (FAM) [10, 11]. Earlier POLM studies reported our core stabilization program was associated with shorter work restriction from LBP [12], and the psychosocial education program resulted in a positive shift in soldier back beliefs [13]. Planned future analyses of the POLM trial include investigation of how core stabilization exercise affects activation of key lumbar musculature, predictors of first episode of LBP, and an economic analysis of these interventions.

The current paper then reports on the primary findings of the POLM cluster randomized trial. The POLM trial had four intervention arms consisting of traditional lumbar exercise, traditional lumbar exercise with psychosocial education, core stabilization exercise, and core stabilization exercise with psychosocial education groups. These intervention groups were compared for their effects in preventing LBP during two years of military duty. The POLM trial's aims were consistent with previously mentioned primary prevention priorities and we investigated individual level effects of exercise and education programs. We hypothesized that soldiers receiving core stabilization and

psychosocial education would have lower incidence of LBP in comparison to those receiving only traditional lumbar exercise.

Methods

The institutional review boards at the Brooke Army Medical Center (Fort Sam Houston, Texas) and the University of Florida (Gainesville, FL) granted ethical approval for this project. All soldiers provided written informed consent prior to their participation. A more detailed description of the POLM trial protocol has been previously published [14]. Data in this paper were reported in compliance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines extension for cluster randomized trials [15].

Subjects

Consecutive soldiers entering a 16-week training program at Fort Sam Houston, TX to become combat medics in the U.S. Army were considered for participation in the POLM trial from February 2007 to March 2008. This training program occurred after completion of basic training.

Subjects were required to be 18 to 35 years of age (or 17-year-old emancipated minors) and be able to speak and read English. Subjects with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the subject to seek health care. Subjects were also excluded if they were currently seeking medical care for LBP; unable to participate in unit exercise due to musculoskeletal injury; had a history of lower extremity fracture (stress or traumatic); were pregnant; or had transferred from another training group. Other possible exclusions included soldiers who were being accelerated into a company already randomized or soldiers who were being re-assigned to a different occupational specialty.

Exercise programs

Subjects performed the assigned group exercise program under the direct supervision of their drill instructors as part of daily unit physical training. Specifically, the entire company exercised at the same time with each individual platoon being led by one of

six drill sergeants assigned to a particular platoon for the training period. Therefore, these exercise programs are likely to pertain to individual, platoon and company levels. The traditional exercise program (TEP) was selected from commonly performed exercises for the rectus abdominus and oblique abdominal muscles. These exercises are routinely performed inside (and outside) the military environment and are utilized to assess physical performance of soldiers [16]. Core stabilization exercise approaches differ in that they target deeper trunk muscles that attach to the spine; such as the transversus abdominus, multifidus and the erector spinae. These muscles play a key supportive role that contribute to the ability of the lumbar spine to withstand loading [17, 18] and exercises that target these muscles are believed to have preventative effects for LBP [8, 9]. The core stabilization exercise program (CSEP) used in the POLM trial consisted of exercises shown with potential to selectively activate these same muscle groups to directly test these purported preventative effects. The TEP and CSEP are described in Table 1 and in more detail in previous POLM publications [12, 16]. The TEP was an active comparison treatment condition because a no-exercise intervention group was not feasible in the military environment.

The TEP and CSEP exercise regimens consisted of five to six exercises, each of which was performed for one minute. Exercise programs were performed daily, for a total dosage time of five minutes per day, five days per week over 12 weeks. Study personnel monitored physical training an average of two days per week over the 12-week training period to answer questions and monitor compliance with the assigned exercise program.

Brief education program

The brief psychosocial education program (PSEP) involved attendance at one session during the first week of training. For the education program, the company was divided into two or three groups to accommodate the size of the lecture hall and also to allow for flexibility in scheduling soldiers. Each group received the same information and the session involved an interactive lecture led by study personnel (ACW, JLD) lasting approximately 45 minutes. The lecture consisted of a visual presentation followed by a question and answer session. The PSEP provided soldiers current, evidence-based

information on LBP that was designed to reduce its threat and fear, such as stressing that anatomical causes of LBP are not likely to be definitely identified and encouraging active coping strategies. Educational material was provided by issuing each soldier *The Back Book* for personal use as has been done in previous trials [19-21]. The PSEP is described in more detail in a previous POLM publication [13]. We did not include a control education program as prior studies consistently demonstrated comparison education approaches did not favorably alter LBP beliefs [19, 20].

Randomization

Military training environments require living in close quarters with other members of the unit, making individual randomization an unfeasible option due to treatment contamination. Therefore, a cluster randomization strategy was utilized as this is a viable methodological choice for large primary prevention trials [22, 23]. The POLM trial had four intervention arms comprised of a combination of the previously described exercise and education programs. The specific intervention combinations for cluster random assignment included TEP only, TEP + PSEP, CSEP only, and CSEP + PSEP.

The randomization schedule was prepared by computer and determined before recruitment began. The randomization schedule was balanced to ensure that equal number of companies was allocated to each program. Treatment allocation was done in a concealed manner at the University of Florida and this process was supervised by our lead statistician (SSW). The randomly generated intervention groups were completed prior to study recruitment and listed in sequential order. This list was then stored on a secure server at the University of Florida. When a new cohort of soldiers was scheduled to start their 12-week training program the study coordinators at Brooke Army Medical Center (ACW, JLD) contacted research personnel at the University of Florida for the appropriate intervention assignment.

Blinding

It was not possible to mask soldiers because they actively participated in the exercise and education training programs. All outcomes were assessed by raters blinded to group assignment or were obtained via self-report.

Baseline measures

Measures were collected under supervision of research personnel unaware of random company assignment and scored in a masked manner by computer algorithm. Soldiers completed standard demographic information, such as age, sex, past medical history, and factors related to military status. Soldiers also completed self-report measures at baseline for physical and mental function [24], anxiety [25], depressive symptoms [26], fear of pain [27], and back beliefs [28].

Outcome measures

We originally intended to assess self-report of LBP incidence using a web-based data collection system, in which soldiers were reminded by email to complete on-line forms about whether they had experienced LBP in the last calendar month [14]. However, one year follow-up rates were much lower than anticipated (18.4%) [29]. Exact reasons for the low follow-up rate from the self-report method were unknown but it could have been due to deployment to Iraq or Afghanistan limiting ability to access the web-based system. At one year follow-up a decision was made to instead measure LBP incidence by tracking soldiers that sought healthcare for LBP. Therefore, the primary outcome for this study is best conceptualized as incidence of LBP that resulted in the seeking of healthcare. This decision to change the method of measuring incidence was based solely on concerns with low follow-up rates noticed before the primary study endpoint [29]. The study team made the decision without the benefit of preliminary analyses and health care utilization was not originally a secondary outcome. Furthermore, only a health care utilization database was considered as the means to generate an alternate measure for LBP incidence. The decision to use a health care utilization database to measure LBP incidence was reinforced when the final two-year self-report response rate remained low at 1,230/4,325 (28.4%).

The Military Health System (MHS) Management Analysis and Reporting Tool (M2 database) was used to determine LBP incidence mainly because of its comprehensive nature in capturing health care utilization. Our interest in using a health care seeking

definition of experiencing LBP was driven by studies indicating continuing high rates of health care utilization for LBP [30, 31] with trends of greatly increasing cost, but of no obvious benefit to the population [32, 33]. In addition, the validity of self-report measures for determining LBP has been questioned for military populations [34], and use of a health care database mitigated these concerns. The M2 database is maintained by the Tricare Management Activity of the MHS and contains a variety of health care data regarding patient care from both the direct care system (care provided in military treatment facilities) and network care (care provided to MHS beneficiaries at civilian facilities) worldwide. Additionally, the data collected to populate the M2 database includes healthcare use while soldiers are deployed to such areas as Iraq or Afghanistan. The M2 database was searched for relevant LBP-related International Classification of Diseases (ICD) codes for soldiers enrolled in the POLM trial. We used similar strategies to operationally define LBP as has been published in other studies, using ICD codes to identify subjects seeking health care for LBP [35, 36]. We had originally planned to investigate the severity of the first LBP episode but the M2 database did not include measures that allowed for such an estimate. Therefore, the severity of LBP outcome measure was abandoned from the reporting of POLM trial primary results.

Sample size estimation and power analysis

This trial intended to recruit a minimum of 16 companies based on the assumption of 150 consenting soldiers per company. A more detailed sample size estimation and power analysis was published with our trial protocol [14].

Data analysis

There were no planned interim analyses or stopping rules for the POLM trial [14]. All statistical analyses were performed using the SAS software, version 9 (SAS Institute Inc, Cary, North Carolina, United States,1996). Demographic and baseline levels of clinical variables were compared among the four intervention groups using analysis of variance (ANOVA) for means and chi-square tests for proportions. Variables that

differed between the four intervention groups were considered in the final analyses, in addition to pre-specified covariates of gender and age.

The incidence of LBP resulting in the seeking of health care data was analyzed with a generalized linear mixed model and the response variable was the number of months in which a soldier reported LBP. Because this was a cluster randomized trial we considered company as a random effect. The planned fixed effects were treatment group, age and gender, as well as any variables that differed among the four intervention groups after randomization. Survival time to the first day of LBP was investigated with a Cox proportional hazards model and log-rank test to investigate treatment effects. The response variable was time to first day in which treatment for LBP was identified in the M2 database using the date of enrollment as the starting point. The predictor variables for the survival analysis were the same variables included in the generalized linear mixed models.

Results

Figure 1 provides information on study enrollment, assignment to the four intervention arms, participation, follow-up, and analysis for all stages of the POLM trial [15]. There were no reported adverse events for the education and exercise programs. Table 2 provides baseline characteristics for each of the randomly assigned exercise and education combinations. Baseline differences across individuals in the four companies were found in age, education, income, active duty status and time in the army (Table 2). These differences were controlled for in subsequent analyses and, therefore, all data from the regression models are presented as adjusted estimates.

Low back pain incidence resulting in seeking of health care

Over two years the number of soldiers captured in the M2 database was 4,147/4,325 (95.9%), and, of those, 706 (17.0%) had LBP resulting in seeking of health care. Lower incidence of LBP resulted from the combination of any exercise with education (CSEP + PSEP and TEP + PSEP). Table 3 shows LBP incidence by percentage for all 20

individual companies (coefficient of intracluster correlation of 0.0053). Table 3 also shows the incidence data by the four randomly assigned intervention groups on which the primary analyses were completed.

The analyses of the four intervention groups suggested a pattern that allowed for more efficient communication of results by collapsing the intervention groups into those receiving any core stabilization (CSEP – yes or no) or any psychosocial education (PSEP – yes or no). There were no differences between the TEP + PSEP and CSEP + PSEP groups, but chi-square test indicated that receiving the PSEP program with any exercise program was protective of LBP incidence (Chi-square = 5.56, P = 0.018; and 5.05, P = 0.025 when adjusted for intracluster correlation) in comparison to those not receiving PSEP. Furthermore, after adjusting for demographic and baseline levels of clinical variables, the protective pooled effect of any PSEP was estimated at 3.3% (95% CI: 1.1 to 5.5%) decreased LBP incidence over two years (P = 0.007). This effect corresponds to numbers needed to treat (NNT) of 30 (95% CI = 18.2 to 90.9).

Results from the generalized linear mixed model indicated that soldiers in the combined exercise and psychosocial education groups (CSEP + PSEP and TEP + PSEP) were similar, but experienced an average of 0.49 fewer months with incidence of LBP (95% CI: 0.003 to 0.983, P = 0.048) in comparison to those not receiving PSEP. Survival analysis on the time to the first day of LBP demonstrated a similar pattern (Figure 2), where the preventative effect of any psychosocial education was observed (hazard ratio = 0.90; Log-Rank test, P = 0.021).

Discussion

The POLM cluster randomized trial is the first large scale trial to test the purported primary prevention effects of core stabilization, alone and in combination with psychosocial education, for LBP. Trial results suggest no benefit of core stabilization exercises for preventing LBP incidence resulting in the seeking of health care in comparison to traditional lumbar exercises. In contrast, a brief psychosocial education program in combination with either of the exercise programs resulted in lower two-year

incidence of health care-seeking for LBP. These results have potential importance for primary prevention strategies for soldiers in the military given the high rates of evacuation due to musculoskeletal pain and injuries that adversely affects soldier preparation [1, 2].

The overall decrease in LBP from brief psychosocial education might be perceived as small, but the 3.3% decrease represented the absolute risk reduction, whereas the relative risk reduction was approximately 17%. Furthermore, seeking health care for LBP is very common [30, 31], so even small decreases in LBP incidence could potentially lessen the burden on a health care system. The psychosocial education program was administered in a single, low-cost session. There is potential for similar education programs to be done in an efficient manner, such that when applied to populations they yield incremental decreases in LBP incidence. Prevention of health care seeking by education seems especially relevant when increased usage and expenditures of health care for LBP have not resulted in obvious improvements in population outcomes [32, 33].

The primary limitation of the current study is that these results may have limited direct application to civilian populations due to trial implementation in a military setting. For example, an alternate explanation for the null effects of core stabilization exercise could be that soldiers in this trial were at high levels of general fitness and not likely to benefit from additional exercise. Another limitation is that the current study did not include a true control condition so we cannot comment on the absolute effects of the exercise programs. We did have a randomly selected group of soldiers who received additional attention from a physical examination and ultrasound imaging [14]. There were no differences in LBP incidence for these soldiers, suggesting no general attention effect in this trial (Table 2).

The decision to shift from a self-report definition of LBP incidence to a definition based on seeking of health care is another limitation to consider. As previously noted, this decision was made before the planned end of the study, was not based on any interim

analyses, and was not a process of choosing one outcome from multiple potential outcomes. However, the end result of this decision is that our incidence measure of LBP resulting in the seeking of health care was not based on self-report of symptoms and had close to 96% follow-up at two years. There is the potential that these findings could underestimate the effect of these interventions on mild LBP episodes that did not necessitate health care and also we were not able to further describe the utilization of health care. For example, we could not distinguish between services that were provided for care during the episode. Overall, however, we feel the shift to a LBP incidence definition that accounted for health care seeking provided an unintended positive dimension to the POLM trial. The individual differences after cluster randomization could have led to systematic effects based on the company, rather than the assigned education program. However, we had low intracluster correlations suggesting independence between clusters and outcome measure. Baseline cluster differences were also small in magnitude (Table 2) and we accounted for company as a random effect in all analyses. Therefore, we are confident that individual cluster effects are fully accounted for when presenting the results.

Another weakness of this study is that soldiers did additional sit-ups to prepare for fitness testing and this training could have adversely affected the core stabilization exercise [12, 16]. However, the rate of additional sit-ups was equivalent across the four groups so any additive effects of extra training would likely have had an equal impact on outcomes. We took a pragmatic approach to exercise dosing and it could be argued that dosage parameters for core stabilization were not sufficient to generate a preventative effect. However, our dosing parameters were consistent with expert recommendations for core stabilization exercise [37]. Furthermore, we did not facilitate or track exercise performance of any kind after the 12-week training period and that is another weakness to consider. Finally, we did not determine if the LBP episode resulted in medical board (disability) or evacuation for soldiers with LBP and this outcome measure would be of importance for future prevention studies.

A strength of the POLM trial is that we recruited a large inception cohort of soldiers not previously experiencing LBP. This factor was highlighted as a research priority for LBP

prevention studies in the European Guidelines [6] and the application of potentially preventative interventions before deployment was consistent with recent military recommendations [1, 2]. Two-year follow-up of all LBP episodes is an additional strength of the POLM trial. Finally, use of a health care utilization database to define LBP incidence is a strength of the study because of increased utilization trends for LBP [30-33] and concerns with using self-report definitions in military samples [34]. Readers should realize, however, that this was a specific way of determining LBP incidence and the results of the POLM trial may not generalize to other ways of determining LBP incidence (for example, survey methods).

Exercise and education for primary prevention of LBP has received mixed support from the European Guidelines [6] and systematic reviews of work place interventions [5, 38]. Individual trials have suggested some types of exercise may be preventative of LBP when compared to no intervention [39], but similar effects have been reported when exercise was compared to patient education [40]. In the POLM trial, two different exercise approaches targeting trunk musculature were compared and there was no benefit from performing specific core stabilization as we had hypothesized. The POLM trial findings are, therefore, consistent with Guideline recommendations [6] that indicate no added benefit of a particular focused exercise approach for prevention of LBP. Future studies investigating primary prevention of LBP may consider different methods for delivering exercise, such as tailored individualized approaches that have demonstrated efficacy for treatment of patients with chronic LBP [41].

The POLM trial did provide data indicating that psychosocial education based on the FAM has potential value for decreasing incidence of LBP resulting in the seeking of health care. Similar positive effects for LBP of psychosocial patient education based on the FAM have been reported in quasi-experimental studies in Australia [42] and France [21]. Although there is some evidence that FAM factors have limited prognostic value in acute stages of LBP [43], these educational studies provide evidence of benefit either before pain [42] or in the acute stage of LBP [21]. What the previously reported education studies do not often address is processes that may account for the benefit. In the case of the POLM trial, we did perform a planned preliminary analysis to investigate

the short term efficacy of our psychosocial education program for a proximal endpoint that occurred after their 12-week training but before deployment [13]. In this preliminary analysis, soldiers receiving the psychosocial education program reported improved beliefs related to the inevitable consequences of LBP as measured by the Back Beliefs Questionnaire [13]. In contrast, soldiers not receiving the psychosocial education program had a slight worsening of their beliefs of LBP. It, therefore, could be asserted that a positive shift in beliefs about LBP while an individual is pain-free may result in decreased likelihood to seek health care when LBP was later experienced during military deployment. This earlier study provides data to support a process to explain the primary findings of the POLM trial, but we did not collect LBP beliefs with the Back Beliefs Questionnaire during the episode of LBP, so we lack the long term data that would directly validate this process.

There are unanswered questions and future research directions to consider following the POLM trial. Future studies could consider testing the preventative capability of core stabilization in different populations with lower overall fitness levels. Also, determining if the psychosocial education program translates to different civilian settings would be of particular interest as there are other trials that have demonstrated positive shifts in LBP beliefs for school age children [44] and older nursing home residents [45]. This particular psychosocial education program used in the POLM trial has potential to generate cost-savings for those seeking health care for LBP, especially if it prevents exposure to expensive interventions that have questionable efficacy [32]. Finally, we used what could be considered a small dose of psychosocial education with no reinforcement after the initial session [13]. Different dosages and reinforcement strategies for the education program could be explored in future studies to determine if larger effect sizes are observed for primary prevention of LBP.

Conclusions

The European Guidelines for Prevention of Low Back Pain [6] indicated a high priority for rigorous randomized clinical trials that investigate primary prevention of LBP. Completion of the POLM trial meets this priority and has provided additional data for

those interested in primary prevention of LBP. Specifically, our results suggest that exercise programs that target core lumbar musculature may offer no additional preventative benefit when compared to traditional lumbar exercise programs. Also, brief psychosocial education may be an important adjunct to exercise programs as they may prevent the seeking of health care when experiencing LBP. These are novel findings and, since this study was done in a military setting, future research is necessary to determine whether these education programs could be implemented in civilian populations with similar efficacy. In addition, future studies should consider the cost-benefit of education programs that reduce LBP incidence resulting in the seeking of health care.

Abbreviations

CONSORT, Consolidated Standards of Reporting Trials; CSEP, core stabilization exercise program; FAM, Fear-Avoidance Model of Musculoskeletal Pain; ICD, International Classification of Diseases; LBP, low back pain; MHS, Military Health System; NNT, numbers needed to treat; POLM, Prevention of Low Back Pain in the Military; PSEP, psychosocial education program; TEP, traditional exercise program

Competing interests

The authors have no competing interests to declare with submission of this manuscript. All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf and these forms are available on request from the corresponding author. All authors received financial support from the Department of Defense to complete the submitted work; have no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; and have no other relationships or activities that could appear to have influenced the submitted work.

Authors' contributions

SZG, JDC, DST, SSW and MER were responsible for the initial conception of the research question, securing funding, supervising the protocol, and final manuscript

preparation. SSW was primarily responsible for data analysis, interpretation and reporting, while SZG, JDC, DST and MER assisted with interpretation and reporting. ACW and JLD were responsible for implementing the study protocol. All authors read, edited and approved the final version of the manuscript.

Acknowledgements

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Figure legends

Figure 1. Flow diagram for patient recruitment and randomization.

Figure 2. Percent of soldiers reporting incidence of low back pain (unadjusted data).

Tables

Table 1. Description of core stabilization (CSEP) traditional (TEP) and exercise programs

Exercise	CSEP	TEP
Principle	Lower load, less repetitions	Higher load, more repetitions
Activation	Slower	Faster
Trunk movements	None to minimal	Full
Dosage	Five minutes/day	Five minutes/day
#1	Abdominal drawing-in maneuver crunch	Traditional sit-up
#2	Left and right horizontal side support	Sit-up with left trunk rotation
#3	Hip flexor squat	Sit-up with right trunk rotation
#4	Supine shoulder bridge	Abdominal crunch
#5	Quadruped alternate arm and leg	Traditional sit-up

CSEP, core stabilization exercise program; TEP, traditional exercise program

Table 2. Comparison of baseline characteristics across the intervention groups

Variable	Label	Overall	TEP	TEP+PSEP	CSEP	CSEP+PSEP	P-Value
		N = 4,325	N = 1,216	N = 952	N = 1,096	N = 1,061	
Innate characteristics							
Age		22.0 ± 4.2	21.6 ± 4.1	22.6 ± 4.5	21.8 ± 4.0	22.1 ± 4.3	<0.0001
Gender	Male	3,082	870 (71.7%)	689 (72.5%)	758 (69.5%)	765 (72.7%)	0.335
	Female	1,226	344 (28.3%)	262 (27.5%)	333 (30.5%)	287 (27.3%)	
Race	Black or Africa	420	104 (8.6%)	88 (9.3%)	114 (10.4%)	114 (10.8%)	0.236
	Hispanic	426	128 (10.5%)	97 (10.3%)	115 (10.5%)	86 (8.1%)	
	White or Caucas	3,190	897 (73.8%)	711 (75.2%)	797 (72.8%)	785 (74.1%)	
	Other	279	86 (7.1%)	50 (5.3%)	69 (6.3%)	74 (7.0%)	-
Education	High school or lower	1,935	600 (49.3%)	409 (43.0%)	484 (44.2%)	442 (41.7%)	0.0038
	Some college	1,998	504 (41.4%)	463 (48.6%)	506 (46.2%)	525 (49.5%)	
	College or higher	391	112 (9.2%)	80 (8.4%)	105 (9.6%)	94 (8.9%)	
Income	Less than $20,000	2,125	620 (51.2%)	418 (44.0%)	583 (53.3%)	504 (47.7%)	0.0001

	Greater than $20,000	2,188	592 (48.8%)	532 (56.0%)	511 (46.7%)	553 (52.3%)	
Active Duty	Active	2,532	725 (59.6%)	504 (52.9%)	737 (67.4%)	566 (53.4%)	<0.0001
	Reserve	1,782	491 (40.4%)	446 (46.8%)	356 (32.5%)	489 (46.1%)	
	Other	8		2 (0.2%)	1 (0.1%)	5 (0.5%)	
Time In Army	<5 months	2,691	768 (63.2%)	566 (59.5%)	737 (67.4%)	620 (58.5%)	<0.0001
	5 months to 1 year	969	276 (22.7%)	198 (20.8%)	222 (20.3%)	273 (25.8%)	
	More than 1 year	661	172 (14.1%)	188 (19.7%)	134 (12.3%)	167 (15.8%)	
Height		68.3 ± 3.9	68.4 ± 3.7	68.4 ± 3.8	68.1 ± 4.0	68.4 ± 4.0	0.340
Weight		164.8 ± 27.7	164.8 ± 26.7	165.7 ± 28.2	163.8 ± 27.9	165.2 ± 28.0	0.426
BMI		24.8 ± 3.1	24.7 ± 3.0	24.8 ± 3.3	24.7 ± 3.2	24.7 ± 3.2	0.807
Psychological							
BDI Total		6.4 ± 6.6	6.5 ± 6.9	6.4 ± 6.7	6.5 ± 6.5	6.3 ± 6.2	0.843
FPQ Total		18.1 ± 5.9	17.8 ± 5.9	18.2 ± 5.9	18.0 ± 6.1	18.2 ± 5.6	0.317
BBQ Total		43.4 ± 7.1	43.3 ± 7.2	43.1 ± 6.9	44.0 ± 6.8	43.2 ± 7.2	0.010
STAI		36.0 ± 9.1	36.2 ± 9.5	35.8 ± 9.1	35.7 ± 9.0	36.3 ± 9.0	0.337

Baseline health status and physical activity

SF 12 PCS		53.4 ± 5.2	53.7 ± 5.0	53.5 ± 5.0	53.4 ± 5.3	53.1 ± 5.2	0.041
SF 12 MCS		49.2 ± 8.6	49.2 ± 8.7	49.1 ± 8.7	49.2 ± 8.5	49.0 ± 8.5	0.938
Smoke Prior to Army	Yes	1,552	442 (36.3%)	354 (37.2%)	374 (34.2%)	382 (36.0%)	0.534
	No	2,771	774 (63.7%)	598 (62.8%)	720 (65.8%)	679 (64.0%)	
Exercise Routinely	Yes	2,220	627 (51.6%)	474 (49.8%)	560 (51.2%)	559 (52.7%)	0.647
	No	2,102	589 (48.4%)	477 (50.2%)	534 (48.8%)	502 (47.3%)	
Attention/Relational Effect							
Physical Exam	No	3,951	1,128 (92.8%)	855 (89.8%)	1,005 (91.7%)	963 (90.8%)	0.087
	Yes	374	88 (7.2%)	97 (10.2%)	91 (8.3%)	98 (9.2%)	

BBQ, Back Beliefs Questionnaire; BDI, Beck Depression Inventory; BMI, body mass index; CSEP, core stabilization exercise program; FPQ, Fear of Pain Questionnaire (9 items); PSEP, psychosocial education program; SF 12 MCS, Mental Component Summary Score from the Short Form Medical Survey (12 items); SF 12 PCS, Physical Component Summary Score from the Short Form Medical Survey (12 items); STAI, State Trait Anxiety Inventory (state portion only); TEP, traditional exercise program

Table 3. LBP rate by company based on utilization data

Training Group	Company	N	Number (%) of Soldiers with LBP incidence resulting in seeking of health care
TEP	1	191	30 (15.7%)
	2	252	41 (16.3%)
	3	228	37 (16.2%)
	4	297	59 (19.9%)
	5	248	46 (18.5%)
	All	1216	213 (17.5%)
TEP + PSEP	1	272	36 (13.2%)
	2	85	12 (14.1%)
	3	229	39 (17.0%)
	4	103	15 (14.6%)
	5	263	30 (11.4%)
	All	952	132 (13.9%)
CSEP	1	250	44 (17.6%)
	2	271	33 (12.2%)
	3	239	50 (20.9%)
	4	269	55 (20.4%)
	5	67	11 (16.4%)
	All	1096	193 (17.6%)
CSEP + PSEP	1	217	37 (17.1%)
	2	183	26 (14.2%)
	3	193	29 (15.0%)
	4	201	35 (17.4%)
	5	267	41 (15.4%)
	All	1061	168 (15.8%)

CSEP	Yes	2157	361(16.7%)
	No	2168	345 (15.9%)
PSEP	Yes	2013	300 (14.9%)
	No	2312	406 (17.6%)

Data presented in the table are unadjusted. Total intervention groups are in bold. The intracluster correlation coefficient (ICC) is 0.0053. For the test of equal LBP rate across intervention groups, comparing TEP Yes vs No, and comparing PSEP Yes vs No, the Chi-Square values equal to 6.99, 0.54, and 5.56; with corresponding *P*-values of 0.0722, 0.4641 and 0.0183, respectively. Adjusting for ICC, the Chi-square values reduce to 6.35, 0.49, and 5.05; with corresponding *P*-values of 0.0957, 0.482 and 0.0246, respectively.
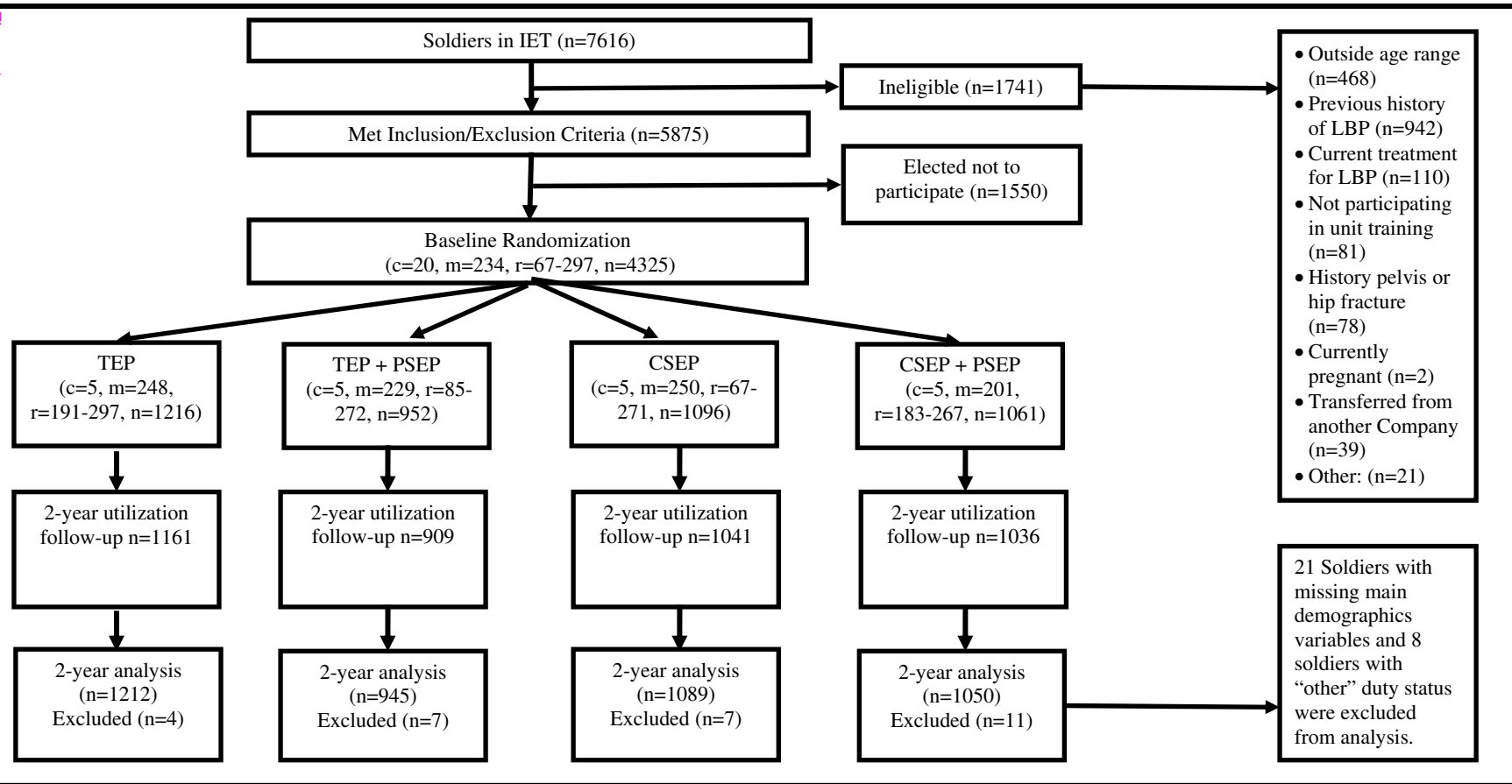
Figure 1

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┌─────────────────────────────────────────┐                                    ┌──────────────────────────┐
│        Soldiers in IET (n=7616)          │                                    │ • Outside age range      │
└─────────────────────────────────────────┘                                    │   (n=468)                │
                    │                          ┌──────────────────────┐         │ • Previous history       │
                    ├─────────────────────────►│ Ineligible (n=1741)  │         │   of LBP (n=942)         │
                    ▼                          └──────────────────────┘         │ • Current treatment      │
┌─────────────────────────────────────────┐                                    │   for LBP (n=110)        │
│ Met Inclusion/Exclusion Criteria (n=5875)│                                    │ • Not participating      │
└─────────────────────────────────────────┘                                    │   in unit training       │
                    │                          ┌──────────────────────┐         │   (n=81)                 │
                    ├─────────────────────────►│ Elected not to       │         │ • History pelvis or      │
                    ▼                          │ participate (n=1550) │         │   hip fracture           │
┌─────────────────────────────────────────┐   └──────────────────────┘         │   (n=78)                 │
│        Baseline Randomization            │                                    │ • Currently              │
│   (c=20, m=234, r=67-297, n=4325)        │                                    │   pregnant (n=2)         │
└─────────────────────────────────────────┘                                    │ • Transferred from       │
                                                                                │   another Company        │
                                                                                │   (n=39)                 │
                                                                                │ • Other: (n=21)          │
                                                                                └──────────────────────────┘
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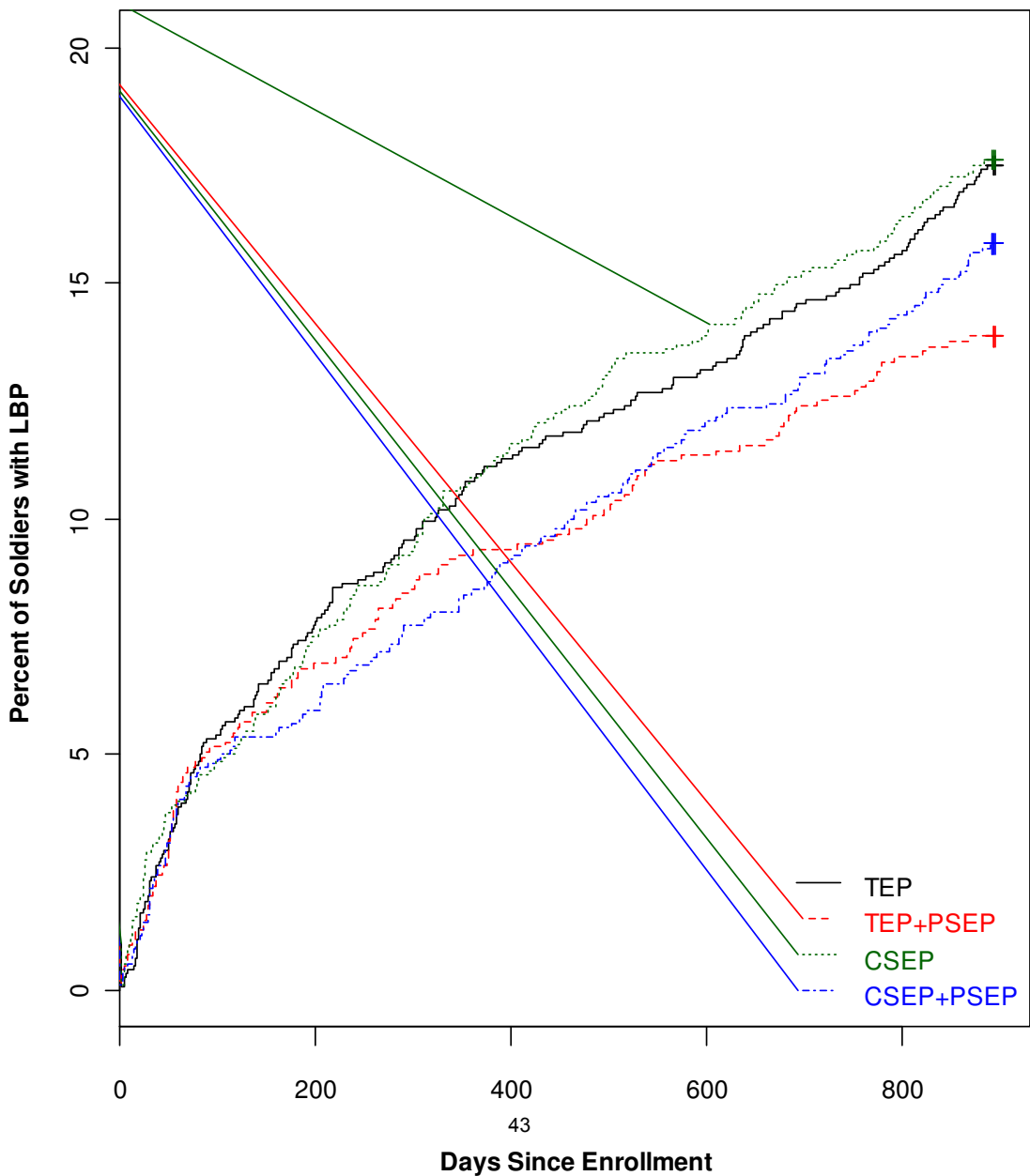
Figure 2

BMC
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RESEARCH ARTICLE

Open Access

Predictors of web-based follow-up response in the Prevention of Low Back Pain in the Military Trial (POLM)

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Abstract

Background: Achieving adequate follow-up in clinical trials is essential to establish the validity of the findings. Achieving adequate response rates reduces bias and increases probability that the findings can be generalized to the population of interest. Therefore, the purpose of this study was to determine the influence of attention, demographic, psychological, and health status factors on web-based response rates in the ongoing Prevention of Low Back Pain in the Military (POLM) trial.

Methods: Twenty companies of Soldiers (n = 4,325) were cluster randomized to complete a traditional exercise program including sit-ups (TEP) with or without a psychosocial educational program (PSEP) or a core stabilization exercise program (CSEP) with or without PSEP. A subgroup of Soldiers (n = 371) was randomized to receive an additional physical and ultrasound imaging (USI) examination of key trunk musculature. As part of the surveillance program, all Soldiers were encouraged to complete monthly surveys via email during the first year. Descriptive statistics of the predictor variables were obtained and compared between responders and non-responders using two sample t-tests or chi-square test, as appropriate. Generalized linear mixed models were subsequently fitted for the dichotomous outcomes to estimate the effects of the predictor variables. The significance level was set at .05 a priori.

Results: The overall response rate was 18.9% (811 subjects) for the first year. Responders were more likely to be older, Caucasian, have higher levels of education and income, reservist military status, non smoker, lower BMI, and have received individualized attention via the physical/USI examination (p < .05). Age, race/ethnicity, education, military status, smoking history, BMI, and whether a Soldier received the physical/USI examination remained statistically significant (p < .05) when considered in a full multivariate model.

Conclusion: The overall web based response rate during the first year of the POLM trial was consistent with studies that used similar methodology, but lower when compared to rates expected for standard clinical trials. One year response rate was significantly associated with demographic characteristics, health status, and individualized attention via additional testing. These data may assist for planning of future trials that use web based response systems.

Trial Registration: This study has been registered at reports at http://clinicaltrials.gov (NCT00373009).

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Background

Achieving adequate follow-up in clinical trials is essential to establish the validity of study findings and reduce bias, helping to insure that the findings can be generalized to the population of interest and more accurately inform clinical decision-making. Studies with low follow-up rates potentially confound interpretation of the results since subjects who drop out may be materially different from those who complete the study (i.e. attrition bias)[1]. Low subject response rates can further threaten external validity by impairing the ability of researchers to make clear scientific conclusions based on their data [1]. According to Straus et al, follow-up rates that exceed 95% minimize the potential for attrition bias to exist whereas follow-up rates lower than 80% pose a threat to external validity [2,3]. Even small losses to follow-up can bias a study's results if few individuals have the outcome of interest. Collectively, these issues make it imperative that clinical trials be conducted in a manner to maximize retention.

One of the most commonly reported factors to be associated with improving retention and follow-up is the attention afforded to subjects during their participation in the study [4]. Dias et al found that increased attention in the form of staff friendliness, responsiveness, and subject encouragement positively influenced long-term follow-up, with retention rates of 98.5% for their 3 year study [4]. Alternatively, Loftin et al found that failing to follow-up with subjects consistently and develop caring and trusting relationships with study participants negatively impacted retention [5]. One might presume that increased attention at an individual level (ie, physical examination, interview, etc.) might translate into improved retention and follow-up compared to group-based attention (ie, educational class) because of the potential to form a deeper connection with subjects in a one-to-one environment compared to a group setting. The experimental groups in the Loftin studies received both group and individual attention through dietary classes and weekly phone calls, respectively, hence they were unable to determine whether increased individual attention is superior to group-based attention [5]. Further studies are needed to determine the influence of attention, especially analyses that allow for comparison of different forms of attention.

A number of other factors have also been purported to positively influence long-term follow-up. These include age over 60, those with lower baseline self-efficacy, and a participant's belief in the merits of the study [6]. Loftin et al found that subjects with higher rates of follow-up had stronger beliefs about the extent to which the study significantly contributed to the community and the advancement of science [5]. Conversely, a number of factors have been shown to negatively influence retention in trials. Janson et al conducted a study on 35 subjects who had voluntarily withdrawn from a large, multi-center randomized trial [7]. The primary factor found to be associated with decreased retention was a perceived lack of sensitivity on the part of the research staff. There were also a few demographic characteristics commonly associated with subject withdrawal to include younger individuals and ethnic minorities. While these factors tended to influence drop-out rates, they did not achieve statistical significance secondary to lack of power as a result of the small sample size of 35 [7]. Other studies have reinforced the notion that demographic factors are not highly predictive of drop-out rates. For example, a large RCT with over 2,311 subjects failed to detect a relationship between BMI, sex, ethnicity, and retention at one year follow up [6].

Further research is needed to identify potentially important factors that influence follow-up rates. Then these factors could be appropriately considered when designing clinical trials. As part of the ongoing Prevention of Low Back Pain in the Military (POLM) trial, we utilized a novel web-based surveillance system to track subject response rate and record incidence and severity of low back pain (LBP) episodes among a group of geographically dispersed Soldiers in the U.S. Army over a 2-year period [8]. As part of the trial, we had access to many baseline variables previously found to be associated with follow-up rates in trials. Therefore, the purpose of this secondary analysis was to determine predictors during the first year of web-based response rates in the POLM trial. We hypothesized that subjects receiving increased attention via a randomly selected education program or physical examination session would have higher follow-up rates than those receiving less attention. We also sought to determine the influence of various demographic, psychological, and health status factors on web-based response rates.

Methods

Design Overview

This study reports a planned secondary analysis in the Prevention of Low Back Pain in the Military clinical trial (NCT00373009) which has been registered at http://clinicaltrials.gov[8]. Consecutive subjects entering a 16-week training program at Fort Sam Houston, TX to become a combat medic in the U.S. Army were considered for participation. In the primary trial, 20 companies of Soldiers were cluster randomized to complete one of 4 training programs: a traditional exercise program including sit-ups (TEP) with (n = 945) or without (n = 1,212) a psychosocial educational program (PSEP) or a core stabilization exercise program (CSEP) with (n = 1,049)

or without PSEP (n = 1,089)[9,10]. Subjects in each of the 4 groups performed the assigned exercise program in a group setting under the direct supervision of their drill instructors as part of daily unit physical training [8,11,12]. Subjects are currently being followed monthly for two years using a web-based surveillance system to record incidence and severity of subsequent LBP episodes. However, the primary trial results are not yet available. For this analysis, we collapsed the study into a single cohort for the purpose of determining predictors of 1-year response rates to the web-based follow-up survey.

Setting and Participants

Research staff at Fort Sam Houston, Texas introduced the study to individual companies of Soldiers and obtained written informed consent. Refer to Figure 1 for a flow diagram describing the number of companies and Soldiers considered for this trial, eventually enrolled into the trial, and completed the 1-year web-based follow-up survey, as per the Consolidated Standards of Reporting Trials (CONSORT) guidelines [9]. All subjects were recruited during a training orientation session attended by all Soldiers as part of their in-processing for medic training. For 8 consecutive months subjects were screened for eligibility according to the inclusion/exclusion criteria. Subjects were required to be 18-35 years of age (or 17 year old emancipated minor), participating in training to become a combat medic, and be able to speak and read English. Subjects with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the

subject to seek health care. Subjects were also excluded if they were currently seeking medical care for LBP; unable to participate in unit exercise due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand; had a history of fracture (stress or traumatic) in proximal femur, hip, or pelvis; were pregnant; or if they had transferred from another training group. Other possible exclusions included Soldiers who were being accelerated into a Company already randomized and recruited for participation in the Prevention of Low Back Pain in the Military trial or Soldiers who were being re-assigned to an occupational specialty other than a combat medic.

Ethics Approval

The institutional review boards at the Brooke Army Medical Center (San Antonio, TX) and the University of Florida (Gainesville, FL) granted approval for this project. All subjects provided written informed consent prior to their participation.

Potential Predictors of Response Rates to the Web-based Survey
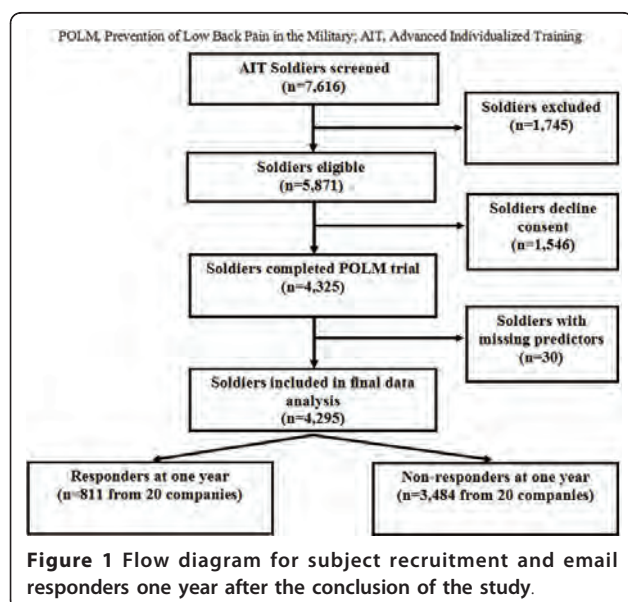
Select demographic characteristics, psychological variables, health status and physical activity, injury status, and attention/relationship effect variables were considered as potential predictors of 1-year response rates on the web-based follow-up survey. These measures were collected at baseline using a variety of commonly utilized and previously validated self-report questionnaires and physical examination procedures performed by research personnel unaware of randomization assignment at baseline. All measures were scored in a masked manner by computer algorithm.

Demographic Characteristics

Demographic characteristics were considered as both a) potential predictors of response rate and b) risk adjustment variables. These characteristics included age, sex, race/ethnicity, level of education, income, length of service, military status, and assigned Company drill instructors.

Psychological Variables

The Back Beliefs Questionnaire (BBQ) is a previously validated self-report questionnaire used to quantify beliefs about the likely consequences of having LBP. Higher BBQ scores are indicative of better LBP beliefs and indicate the potential of a better ability to cope with LBP [13]. The State-Trait Anxiety Questionnaire (STAI) and Beck Depression Inventory (BDI) were used to measure negative affect from generalized anxiety and generalized depression, respectively [13]. Higher scores on these indices were indicated of higher anxiety and

Figure 1 Flow diagram for subject recruitment and email responders one year after the conclusion of the study.

depressive symptoms. Nine items from the Fear of Pain Questionnaire (FPQ-III) were used to measure fear about specific situations that normally produce pain [13]. Higher scores on the fear indices indicated higher general fear of pain and fear of low back pain.

Health Status and Physical Activity

The Medical Outcomes Survey 12-Item Short-Form Health Survey (SF-12) was used as a self-report of health status for physical and mental function. The physical and mental component summary scales (PCS and MCS) were reported individually in this study because they are valid estimates of physical and mental health [13].

As part of the intake questionnaire, Soldiers were queried as to their level of physical activity prior to entering training. Specifically, Soldiers were asked to report how many days per week on average they performed at least 30 minutes of exercise and how many years over the course of their lifetime they have consistently exercised at least 3 days per week prior to entering training. Soldiers were queried regarding their smoking status, and their body mass index (BMI) was calculated [8].

Attention/Relationship Effect

Psychosocial Educational Program Soldiers who were randomized to PSEP (n = 1994) completed an educational session within a group setting during the first 14 days of entering training. The session consisted of an interactive seminar designed by the POLM investigative team and was implemented by study personnel. The overall goal of the 45 minute session was to emphasize current scientific evidence on LBP based on biopsychosocial principles that promote healthy beliefs about LBP. The seminar covered topics related to the favorable natural history of LBP, lack of definitive anatomical causes of LBP, the importance of returning to normal activity, and decreasing fear-avoidance beliefs and pain catastrophizing when experiencing LBP. Soldiers were informed why educational information on best LBP coping strategies was important despite the fact they did not currently have LBP. After the seminar, Soldiers participated in a question and answer session and were issued The Back Book [8]. The Back Book was used as the educational supplement because of our prior experience with it in a physical therapy clinical trial and its prior association with positive shifts in patient LBP beliefs [13].

Physical Examination of Trunk Musculature Because it would be time and cost prohibitive to perform an extensive physical examination on all subjects in a trial this large, a subgroup of Soldiers from each company (n = 371) were randomized to receive additional testing in the form of a physical and ultrasound imaging (USI) examination of key trunk musculature. The physical examination consisted of measuring low back range of motion, straight leg raise, and bilateral hip range of motion measurements. Soldiers also completed 4 trunk muscle endurance tests (extension, flexion, and bilateral side supports) by determining how long a specific position could be maintained. Separately, a USI examination was performed which included assessment of the lateral abdominal muscles (transverse abdominus, internal and external oblique muscles) during an active straight leg raise and symmetry of the multifidi muscles [8]. The examination required approximately 2 hours. Soldiers who received the physical/USI examination and/or receive the PSEP were classified as having received additional attention for the purpose of assessing the potential for increased attention to influence response rates.

Web-based Follow-up Surveys

At the end of the initial 12 weeks of training, Soldiers were trained in a computer lab on how to use the web-based surveillance system to complete the monthly follow-up surveys. The purpose of the follow-up surveys was to record incidence and severity of subsequent LBP episodes in the previous calendar month. Access to the web-based surveillance system was prompted by an email, which was sent to the Soldier's official military email address on the 1st of each month. The web-based survey started with an email prompting to visit the study hosted, confidential, secure web-site. Once the website was accessed, Soldiers were asked one initial screening question - "have you had any back pain in the past 30 days?" A "no" answer ended the survey and Soldiers were thanked for their participation. A "yes" answer prompted the Soldiers to complete an additional set of 46 items about the back pain episode including duration, impact on work activities, whether health care was sought, and response to standard questionnaires (ie, NPRS, ODQ, FABQ, and PCS). Soldiers were provided their login credentials (user name and password) during the initial training session at the end of the 12-week trial. Login credentials were also provided in the monthly email reminders. If a Soldier did not respond to the first email, an additional email was sent on the 3rd of the month, and again on the 7th of the month if the Soldier still had not responded.

Data Analysis

The primary dependent variable for this paper was the dichotomous outcome of whether a Soldier responded to any one of the 12 monthly surveys. The independent variables considered as potential predictors of response rate included psychological variables (BDI, FPQ, BBQ, STAI), health status and physical activity (SF-12 PCS and MCS total, smoking status, level of physical activity, BMI), and the attention/relationship effect (received physical/USI examination or PSEP). Potential effects of

additional attention in the form of an individualized examination and group attention from the PSEP were examined separately. Other explanatory variables of interest and for risk adjustment included demographic characteristics such as age, sex, race/ethnicity (White/Caucasian, Black/African American, Hispanic, and others), level of education (College or more, Some college, High school or less), income ($>20,000 or more, length of service (<5 months, 5 months-1 year, >1 year), military status (Active duty, Reservist, or National Guard), and assigned Company drill instructors.

Descriptive statistics of the demographic and clinical variables were compared between the responders and non-responders using two sample t-tests or chi-square test, as appropriate. A generalized linear mixed model was then fitted for the dichotomous outcome to estimate the effects of potential predictors and the other explanatory variables listed above. A random company effect was included in the models to accommodate for the correlation among Soldiers within the same company. Furthermore, to assess the response difference over time, we fitted a second generalized linear mixed model using the longitudinal binary outcomes of whether a Soldier responded to each one of the 12 monthly surveys as dependent variable, with quadratic time effect in addition to the same predictor/explanatory variables as in the first model. The significance level was set at .05 a priori, and all analyses were performed with the use of SAS software, version 9.1.

Results

Among the 4,325 Soldiers who completed POLM trial, 4,295 Soldiers (99.3%) had complete data in all predictor variables and included in the final analyses (Figure 1). Among the 4,295 Soldiers, 71% were male, 72% were White/Caucasian, 55% had at least some college or more education, 51% had $20,000 or more household income, 63% had been enlisted in the Army for less than 5 months, and 15% for more than 1 year. The study population had a mean age of 22.0 years (SD = 4.2) (Table 1). The overall response rate to the web-based survey was 18.9% (811 subjects) for the first year of the POLM trial.

Non-responders and responders significantly differed in age, race/ethnicity, education, income, military status, length of service, depression, back beliefs, anxiety, health status, smoking history, BMI, and whether a Soldier received individual attention from the physical/USI examination (all with p < .05, Table 1). Based on the adjusted model (Table 2), the odds of response increased by 5% for every one year increase in age. Black/African American Soldiers had .76 times odds of response compared to White/Caucasian. Compared with Soldiers with college or higher education, the odds of response were

.54 and .70 times for those with high school or less and those with some college education, respectively. Full-time active duty service members had .68 times odds of response compared to those from a Reserve or National Guard unit. The odds of response decreased by 3% for every one unit increase in BMI. Those who did not smoke had 1.69 times odds of response compared to those who smoked prior to entering the Army. In addition, those who did not receive the physical/USI examination had .70 times odds of response compared to those who received the examination. There was no difference in response rate based on whether Soldiers received group attention via the PSEP. The following factors: income, length of service, BDI, BBQ and SF-12 became statistically non-significant after adjusting the previously stated factors (Table 2). In addition, the above effects remained statistically significant in the second generalized linear mixed model that included the quadratic time effect, which indicated that the response rates significantly decreased over the first 12 months of the trial (p < .001, Figure 2).

Discussion

The results of this analysis demonstrated that response rate to the web-based survey was significantly associated with demographic characteristics, health status, and individualized attention via additional testing. Our response rate was low compared to standard randomized clinical trials that incorporate face-to-face contact to secure follow-up data (which typically range from 80-95%[2,3]) and compared to at least one similarly designed study that depended heavily on web-based surveillance systems without direct face-to-face contact with the subject during the follow-up phase of the study [14]. The overall lower response rates observed with web-based surveillance systems compared to more traditional follow-up strategies (ie, phone, face-to-face, etc.) is likely attributable to less subject accountability during the follow-up phase of the study. Soldiers did not have face-to-face contact and accountability for survey completion following the initial training phase of the study, placing more responsibility on the individual Soldiers to complete the online surveys. Although difficult to confirm, it is likely that the geographic dispersion of Soldiers around the world, deployments to austere parts of the world with limited internet access (ie, Iraq/Afghanistan), and subsequent discharge from the Army may have also contributed to the overall decreased response rate. When using web-based surveillance systems, follow-up rates may be further enhanced by supplementing with traditional methods such as phone call centers and querying available databases for health care utilization related to LBP. These combinations of multiple follow-up strategies have the potential to increase overall

Table 1 Statistical analysis of web-based responders and non-responders via during first year follow up from POLM study

Variables	Overall (n = 4,295)	No Response (n = 3,484)	Response (n = 811)	P-value
Age	22.0 (4.2)	21.8 (4.1)	22.8 (4.7)	<.001
Gender				
Female	1233 (28.7%)	978 (28.1%)	255 (31.4%)	.056
Male	3062 (71.3%)	2506 (71.9%)	556 (68.6%)	
Race/Ethnicity				
African American	444 (10.3%)	367 (82.7%)	77 (17.3%)	
Caucasian	3,094 (72.0%)	2,508 (81.1%)	586 (18.9%)	.043
Other	757 (17.7%)	609 (80.4%)	148 (19.6%)	
Education				
High school or lower	1,952 (45.4%)	1,667 (85.4%)	285 (14.6%)	
Some college	1,955 (45.5%)	1,549 (79.2%)	406 (20.8%)	<.001
Graduated from college or higher	388 (9.0%)	268 (69.1%)	120 (30.9%)	
Income				
<$20,000	2,119 (49.3%)	1,750 (82.6%)	369 (17.4%)	
$20,000 or more	2,176 (50.7%)	1,734 (79.7%)	442 (20.3%)	.015
Military Status				
Active	2,518 (58.6%)	2,125 (84.4%)	393 (15.6%)	
Reserve	1,777 (41.4%)	1,359 (76.5%)	418 (23.5%)	<.001
Length of Service <5 months	2,684 (62.5%)	2,232 (83.2%)	452 (16.8%)	
5 months - 1 year	964 (22.4%)	750 (77.8%)	214 (22.2%)	<.001
> 1 year	647 (15.1%)	502 (77.6%)	145 (22.4%)	
Depression (BDI)	6.4 (6.6)	6.5 (6.7)	6.0 (6.1)	.039
Fear of Pain (FPQ)	18.1 (5.9)	18.0 (5.9)	18.2 (5.6)	.452
Back Beliefs (BBQ)	43.4 (7.1)	43.3 (7.0)	44.0 (7.4)	.005
Anxiety (STAI)	36.0 (9.2)	36.2 (9.2)	35.2 (9.1)	.004
Physical Health Status (PCS Total)	53.4 (5.1)	53.4 (5.1)	53.5 (5.2)	.400
Mental Health Status (MCS Total)	49.2 (8.6)	49.1 (8.7)	49.6 (8.0)	.099
Smoke Prior to Army				

Table 1 Statistical analysis of web-based responders and non-responders via during first year follow up from POLM study *(Continued)*

No	2,756 (64.2%)	2,151 (78.0%)	605 (22.0%)	<.001
Yes	1,539 (35.8%)	1,333 (86.6%)	206 (13.4%)	
Company Instructor				
Alpha	621 (14.5%)	494 (14.2%)	127 (15.7%)	
Bravo	929 (21.6%)	766 (22.0%)	163 (20.1%)	
Charlie	607 (14.1%)	497 (14.3%)	110 (13.6%)	
Delta	957 (22.3%)	760 (21.8%)	197 (24.3%)	.256
Echo	660 (15.4%)	531 (15.2%)	129 (15.9%)	
Foxtrot	521 (12.1%)	436 (12.5%)	85 (10.5%)	
BMI	24.8 (3.2)	24.8 (3.2)	24.6 (3.2)	.027
Physical Examination				
No	3,924 (91.4%)	3,202 (81.6%)	722 (18.4%)	.009
Yes	371 (8.6%)	282 (76.0%)	89 (24.0%)	
Psychosocial Educational Program (PSEP)				
No	2,301 (53.6%)	1,871 (81.3%)	430 (18.7%)	
				.726
Yes	1,994 (46.4%)	1,613 (80.9%)	381 (19.1%)	
Exercise Group				
TEP only	1,212 (28.2%)	990 (28.4%)	222 (27.4%)	
TEP+PSEP	945 (22.0%)	767 (22.0%)	178 (21.9%)	
				.932
CSEP only	1,089 (25.4%)	881 (25.3%)	208 (25.6%)	
CSEP+PSEP	1,049 (24.4%)	846 (24.3%)	203 (25.0%)	

POLM, Prevention of Low Back Pain in the Military; BDI, Beck Depression Inventory; BBQ, Back Beliefs Questionnaire; STAI, State-Trait Anxiety Index; SF12, Medical Outcomes Survey 12-Item Short-Form Health Survey; BMI, Body Mass Index; PSEP, Psychosocial Educational Program. The p-values are based on t-tests or chi-square test, as appropriate.

response rates compared to any single strategy alone but need further testing before firm recommendations can be made.

Among health status factors, a Soldier's smoking status was a significant predictor of response rates to the web-based surveillance system. Those who did not smoke prior to entering the Army had a 1.7 times odds of response compared to those who smoked prior to entering the Army (p <.001). This means Soldiers who smoked had 42.0% lower odds of response compared to those w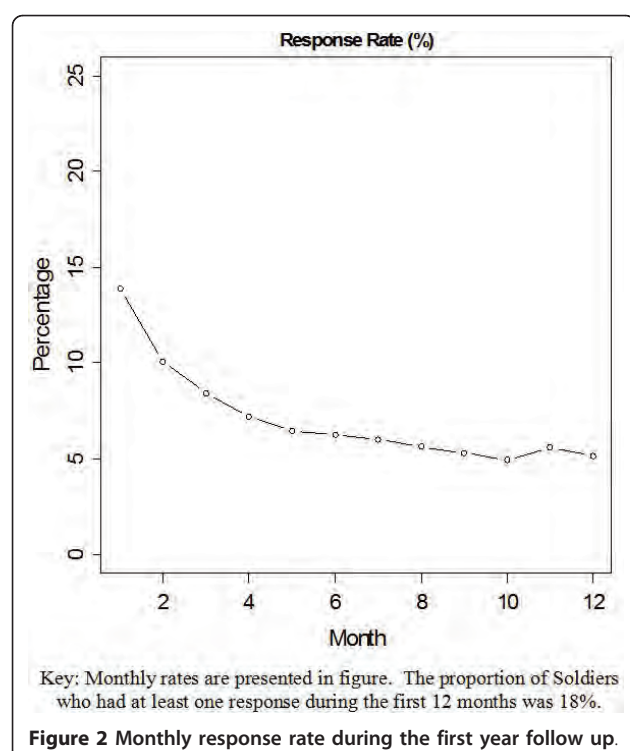ho did not smoke. It is possible that smoking status may be related to other measures of health, yet smoking still emerged as an independent predictor of response rates despite controlling for these factors. Perhaps Soldiers who smoke are less inclined to appreciate the importance of health-related research. This finding is particularly relevant for the POLM trial because 35.8% of Soldiers in this study classified themselves as smokers, defined as individuals who had smoked at least 100 cigarettes in their lifetime. The POLM trial data are consistent with a recent study demonstrating that 32.2% of military personnel are smokers [15]. In contrast,

Table 2 Statistically significant predictors of web-based response from generalized linear mixed model*

Variable	Odds Ratio (95% CI)	P-value
Age	1.05 (1.02; 1.07)	<.001
Race/Ethnicity		
African American vs. Caucasian	.76 (.57; .99)	.046
Education		
High school or lower vs. Graduated from college or higher	.54 (.40; .71)	<.001
Some college vs. Graduated from college or higher	.70 (.54; .91)	.008
Military status		
Active vs. Reserve	.68 (.56; .81)	<.001
Smoke Prior to Army		
No vs. Yes	1.69 (1.41; 2.03)	<.001
BMI		
Increasing 1 unit	.97 (.94; 1.00)	.027
Physical examination		
No vs. Yes	.70 (.54; .90)	.006

*The fitted model included all potential predictors and other pre-specified explanatory variables (see text for details); results for the statistically significant predictors are reported here.

POLM, Prevention of Low Back Pain in the Military; BDI, Beck Depression Inventory; BBQ, Back Beliefs Questionnaire; STAI, State-Trait Anxiety Index; PCS, Physical Component Summary of the SF12, MCS, Mental Component Summary of the SF12, Medical Outcomes Survey 12-Item Short-Form Health Survey; BMI, Body Mass Index; PSEP, Psychosocial Educational Program.

Key: Monthly rates are presented in figure. The proportion of Soldiers who had at least one response during the first 12 months was 18%.

Figure 2 Monthly response rate during the first year follow up.

approximately 21% of the general public among a similar age group are smokers [15]. This indicates that smoking status may need to be considered during study planning, particularly for powering large clinical trials in which the primary outcome may be an infrequent occurrence or when performing studies with a high preponderance of smokers.

Another significant predictor of response rates in the POLM trial was military status, defined as whether the Soldier was in an "active duty" or "reservist" status. Active duty Soldiers had 15.6% response rate compared to 23.5% of those in the reserves (<.001). Although this consideration may have limited applicability beyond the military population, this distinction appears to be an important consideration for designing trials that include military subjects. The reason for the discrepancy in response rates between active duty and reservists is unclear; however, there are several possible explanations for this finding. Many of the training requirements for reservists are completed individually online via a variety of distance-based training platforms given their part time status and geographic separation from their active duty Army counterparts. As a result, the increase in their response rates could be partially explained by their increased familiarity with online training. Although

purely speculative, perhaps reservist personnel also tend to be more self-motivated to complete training requirements because they are more accustomed to not having significant day-to-day oversight and accountability for completing their training requirements, which is closely aligned with the methodology used to administer the web-based follow up for the POLM study. Alternatively, active duty Soldiers tend to complete training requirements in groups settings within environments that have more direct monitoring and accountability. These differences may influence this group to be less likely to respond to the follow-up surveys in the absence of direct accountability.

In addition, higher educational levels were associated with increased response rates on the follow-up survey. Specifically, 20.8% of Soldiers with at least some college education responded compared to 14.6% of those who only completed high school (p <.001). College graduates had the highest response rates at 30.9%. Individuals with a high school education or lower were only .5 times as likely to respond as those with some college, whereas those with some college education were .7 times as likely to respond as college graduates. These results are not surprising since one might suspect that individuals with higher levels of education may have more intrinsic motivation and are therefore more likely to respond [16]. It is also possible that these individuals have a better appreciation for the value of health-related research and importance of subject participation. Furthermore, the increased response rates among Soldier who had completed at least some college may be related to increased computer literacy, which could certainly influence response rates given the web-based platform utilized to assess follow-up in the POLM trial.

Previous research has demonstrated that increased subject attention may enhance follow-up rates in clinical trials, regardless of the follow-up mechanism that is used [4]. To examine the potential for increased attention to enhance response rates in the POLM trial, we examined group and individualized attention. Subjects in the PSEP group who received the additional back education class in a group setting were classified as having received additional group attention, whereas Soldiers randomized to receive the physical/USI examination were classified as having received additional individual attention. The results of this study reinforce conclusions from the existing literature that increased attention during trials may enhance response rates, even when the extra attention is not directly related to completing follow-up procedures. However, a statistically significant enhancement in response rates was only observed among Soldiers who received increased individualized attention. For example, Soldiers receiving individualized attention had response rates of 24.0% compared to 18.4% among those who did not (p = .009). In contrast, receiving group attention was not associated with significant improved response rates. Soldiers receiving PSEP had response rates of 19.1% compared to 18.7% among those who did not (Table 1). Soldiers receiving both PSEP and USI had response rates of 26.4% compared to 21.4% among those receiving USI only, but this difference was not statistically significant due to small sample sizes.

Our results are in contrast to the findings from previous studies that have found increased attention in group settings to be associated with increased follow-up rates [5]. One possible explanation for this discrepant finding is that a large majority of the training completed by Soldiers in the military is done in group settings. Thus it is possible that Soldiers in the PSEP group may have perceived the back education class as an additional training burden, as opposed to value added training designed to improve their ability to cope with back pain. Additionally, the back education class was completed on a Saturday morning outside of the normal training syllabus, which could have been perceived in a more negative light. On the other hand, the physical examinations were substituted for another training requirement rather than additive, increasing the likelihood that Soldiers perceived receiving the examination as a "good deal" because they were exempt from that morning's physical training. Additionally, individualized attention from the examination may have peaked the Soldiers interest and personal appreciation for the study, further building rapport between the Soldiers and study staff, increasing their "buy-in" to the study. Designing trials that include individualized attention is an important consideration for improving response rates in trials, which helps to improve precision of the results and increase overall generalizability of the findings. However, more attention must be paid to the type of attention that provides maximal improvement in response rate, instead of the assumption that any additional attention is value added.

Several limitations for this analysis should be considered. Despite achieving statistical significance, it's possible that some of the findings may be spurious, as evidenced by the questionable meaningfulness of the effect sizes among some of the significant findings, predominantly age, race/ethnicity, and BMI. The confidence intervals of the odds ratios according to our data approximated a value of 1.0, which is equivalent to no increase or decrease in odds of response, thus negating the potential meaningfulness of these findings. As an example, age emerged as a significant predictor of response rates, yet the mean age among responders was 22.8 compared to 21.8 years of age among non responders, resulting in an odds ratio of 1.1. Although this result was statistically significant, one year in age difference does not appear to be a material finding that

might inform the design of future trials. Similar findings were observed for both race/ethnicity and BMI. These small but statistically significant effects can likely be attributed to fact that the original POLM study was powered on the primary aim of detecting future episodes of back pain in the 2 years following completion of training. This may have resulted in an increased chance for Type I error in this secondary analysis.

This study reported predictors of response to a web-based survey using a dichotomous outcome to represent response rate. This decision was made because the primary outcome of the trial is a dichotomous measure (occurrence of low back pain) and we wanted these analyses to be parallel. Our additional analysis showed that response rates significantly decreased over time, which was an expected outcome that is typical in clinical trials. Also, it would be interesting to assess whether internet access was a barrier for some of the Soldiers in this study, in particular those who were deployed in remote settings around the world. However, this information was not available to us, hence we can only speculate that response rates may be lower for those Soldiers who did not internet access during the follow-up phase of the study. Future studies might also examine whether other contemporary methods of communication (ie, SMS text messaging, social media, etc.) might be more effective than email in securing follow-up [17].

Another limitation is that the subjects in this trial were more homogenous compared to the general population. Many of the Soldiers' eating habits, activity levels, and work environments are nearly identical because of the more controlled environment within the military. Similarly, subjects in the military have been shown to have similar psychological profiles [18]. As a result, these factors would not have had the opportunity to compete for explaining additional variance in the response rates, even if some relationship might exist in a more heterogeneous general public. This is potentially the reason why the psychological factors did not remain in the final regression model as predictors of response rates. Finally, the participants in this study were training to become combat medics. One might expect that their response rate would be higher than Soldiers in non-medical fields, similar to how medical personnel demonstrate higher response rates compared to subjects in the general population [19]. However we had no comparison group in the current study so we can only speculate that these follow up rates might be higher than if this study targeted subjects in the general population.

Conclusions

Understanding which factors are associated with response rates can help to improve follow-up by informing the design of clinical trials and improving our understanding of the effectiveness of web-based surveillance systems in large clinical trials among a highly geographically dispersed subject pool. Additional attention during a trial may improve response rates, but optimal strategies have yet to be identified. Future studies should consider how to best incorporate individualized attention within clinical trials to increase response rates. Researchers should also monitor other predictors of follow-up rates identified in this analysis within their clinical trials so that any deferential influence of these factors in response rates can be considered when interpreting the results of their studies.

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Authors' contributions

JDC contributed by developing study design, interpreting data, and composing the manuscript. DST participated in study design and data interpretation. JJV, BFD, BJL, and GLH aided in data interpretation and manuscript composition. SSW performed the statistical analysis and helped in data interpretation. SZG aided in study design and data interpretation. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Inter-Rater Reliability of Ultrasound Imaging of the Trunk Musculature Among Novice Raters

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Objective—The purpose of this study was to determine the inter-rater reliability of ultrasound imaging for assessing trunk muscle morphologic characteristics at rest and while contracted among different pairs of novice raters. The secondary purpose was to compare 3 different measurement techniques for assessing lateral abdominal muscle thickness.

Methods—A single-group repeated measures reliability study was conducted on 21 healthy participants (mean ± SD, 21.5 ± 4.4 years; 5 female and 16 male) without low back pain. Ultrasound images of the transversus abdominis, internal oblique, rectus abdominis, and lumbar multifidus muscles were obtained by different pairs of novice raters in a counterbalanced order. All raters received a standardized training program before obtaining measurements.

Results—The intraclass correlation coefficient (1, 3) point estimates ranged from 0.86 to 0.94; the standard error of the measurement ranged from 0.04 to 0.16 cm for the thickness values and 0.67 cm^2 for the cross-sectional area of the rectus abdominis muscle. There was no meaningful difference between the different measurement techniques used to analyze the lateral abdominal muscles.

Conclusions—Good to excellent reliability was obtained for all measures by novice raters. Minimal differences in reliability were noted between the different measurement techniques to assess lateral abdominal muscle thickness.

Key Words—internal oblique; lumbar multifidus; rectus abdominis; transversus abdominis; ultrasound

Motor control exercise therapy (ie, lumbar stabilization) has been demonstrated to be an effective management strategy for improving pain and function for those with nonspecific low back pain.[1–3] Moreover, researchers have identified a subgroup of patients with low back pain who appear to preferentially benefit from motor control exercises.[4–6] In general, this subgroup comprises individuals with deficits in the deep trunk musculature, such as the transversus abdominis[7–11] and the lumbar multifidus.[12–15] Although researchers have increasingly identified associations between low back pain and underlying neuromuscular control deficits,[16] reliable and valid measurement tools that are noninvasive, provide real-time feedback, and are useful for research and clinical decision making have been scarce.

Recently, researchers have been assessing the role of rehabilitative ultrasound imaging[17] to aid in the evaluation and management of those with low back pain. In a recent systematic review, Koppenhaver et al[18] concluded that ultrasound imaging is a valid measure of trunk muscle size, provides an indirect assessment of muscle activation, and is sensitive to change. From a construct validity perspective, researchers have been able to demonstrate deficits in muscle size (atrophy) and altered activity of the lateral abdominal muscles[4,7–9,19] and the lumbar multifidus.[12,14,15] From a criterion validity perspective, researchers have been able to demonstrate an association between ultrasound imaging measurements of muscle morphologic characteristics with both magnetic resonance imaging and electromyography.[20–23] Additionally, ultrasound imaging can be used to provide real-time feedback to both the provider and the patient about exercise performance and motor learning to aid in rehabilitation.[24–27] Clinically, the role of ultrasound imaging to aid rehabilitation can be appreciated in a recent prospective cohort study by Hides et al.[28] In this study, the researchers were able to demonstrate a decreased cross-sectional area and asymmetry of the lumbar multifidus in elite cricketers with low back pain compared to those without low back pain. Furthermore, they were able to demonstrate that motor control training that included ultrasound guided biofeedback training was able to improve the cross-sectional area and symmetry of the lumbar multifidus muscle at the end of the 13-week training program. These improvements in muscle morphologic characteristics were associated with clinical improvements in the athletes' symptoms.

Although the use of ultrasound imaging in the evaluation of muscle morphologic characteristics and function for low back pain is promising, psychometric properties such as reliability and precision (standard error of the measurement and minimal detectable change) need to be established. In one of the larger reliability studies, Koppenhaver et al[29] demonstrated inter-rater reliability [intraclass correlation coefficient (ICC) (2, 2)] point estimates of 0.80 to 0.94 for assessing lateral abdominal and lumbar multifidus muscle thickness. Additionally, researchers have been able to demonstrate that an average of 3 measures of muscle thickness at rest and while contracted resulted in better reliability and precision compared to a single measurement.[30,31] Although 2 systematic reviews concluded that most studies indicated good reliability, further research is needed.[32,33] One identified limitation has been the same sample size, with most studies having fewer than 10 participants, which has resulted in excessively wide confidence intervals.[32,33] Some of the previous studies also used only a single set of images or failed to repeat the entire measurement procedures between raters, thereby not eliminating other potential sources of error.[32,33] Another current limitation in the existing literature is that reliability assessments have only been completed with the muscle at rest and not while contracted.[33] Mixed results have been reported for measures of reliability and precision when assessed by novice raters.[29,30,34,35] Additionally, most inter-rater reliability studies have compared the same set of assessors.[33] Finally, comparisons of different measurement techniques to assess the lateral abdominal muscles have been scarce.[9,10,29,30,36]

On the basis of the limitations in the existing research regarding the psychometric properties of ultrasound imaging, we attempted to address some of the current gaps for using ultrasound imaging to assess the trunk musculature. The primary purpose of this study was to assess the inter-rater reliability of ultrasound imaging for assessing trunk muscle morphologic characteristics at rest and while contracted among different pairs of novice raters. The evaluation included the transversus abdominis, internal oblique, rectus abdominis, and lumbar multifidus muscles. The secondary purpose was to compare 3 different measurement techniques for assessing lateral abdominal muscle thickness. We hypothesized that measurements of muscle morphologic characteristics obtained by ultrasound imaging would be adequately reliable (ICC > 0.75) and have good measurement precision.

Materials and Methods

Participants

Participants consisted of a subset of US Army soldiers enrolled in a cluster randomized trial on prevention of low back pain in the military.[37] Over a 12-month period, 4325 soldiers undergoing a 16-week training program at Fort Sam Houston, Texas, to become combat medics volunteered to participate in the trial. Soldiers were eligible to participate if they were between 18 and 35 years of age (or emancipated minors), fluent in English, and enrolled in combat medic training. Soldiers were excluded if they had a history of low back pain that resulted in limited work or physical activity greater than 48 hours, seeking medical care, or prior surgery in the lumbar spine region. Soldiers were also excluded if they were unable to participate in unit physical training because of other musculoskeletal injuries, had a history of fracture (stress or traumatic) in the hip and/or pelvis, or were pregnant. Of the 4325 soldiers, a random sample of 200 participants was identified to participate in a physical examination, which included assessment of the abdominal and lumbar multifidus musculature.

This analysis represented a convenience sample of the first 21 participants, who completed a second examination for the purposes of establishing reliability of the study procedures. All participants signed consent forms approved by Brooke Army Medical Center's Institutional Review Board.

Examiners

The examiners who participated in this study were all novice raters and included 2 research physical therapists and 4 physical therapy students enrolled in a doctor of physical therapy training program. Before testing, all examiners underwent training that consisted of 20 hours of hands-on training led by 1 of the coinvestigators (D.S.T.) experienced with the specific ultrasound imaging protocol used in the study. A proficiency evaluation was completed on each rater before data collection.

To minimize bias, investigators worked in pairs. One investigator in each team was designated as the recorder, and the other investigator was designated as the imager. The imager was responsible for positioning the transducer for optimal visualization of the musculature. Both the imager and the recorder had to agree on image quality and placement. If on-screen measurements were obtained, the recorder would annotate measurements and image information. Throughout the process, the imager was blinded to all measurements. Two pairs of raters evaluated each participant; selection of rated pairs was counterbalanced.

Procedures

This study was a single-group repeated measures design. Images of the abdominal and lumbar multifidus muscles were acquired in B-mode using a portable ultrasound unit (Titan; SonoSite, Inc, Bothell, WA) with a 5-MHz, 60-mm curvilinear array using techniques previously outlined.[38,39] Image acquisitions for each muscle (rectus abdominis, transversus abdominis, internal oblique, and lumbar multifidus) and for each testing condition (rest and contracted) were performed 3 times.[31] Two pairs of raters were randomly selected to evaluate each participant. Participants changed plinths and walked between evaluations from each pair of raters. Images were obtained bilaterally; however, the results described are related to the right-sided musculature. A total of 60 images were assessed for each participant, resulting in a total of 1260 images analyzed. To help avoid an order effect, the images outlined below were obtained in a counterbalanced order.

Images of the lumbar multifidus at the L4-5 level were obtained with the participants in the prone position. Pillows were placed under the pelvis to minimize the lumbar lordosis. An inclinometer was used to ensure that the lumbar spine was within 10° of the horizontal.[23,39,40] The transducer was placed longitudinally along the spine, allowing visualization of the sacrum and the caudal lumbar zygapophyseal joints. The transducer was slightly lateral to the spinous process and angled slightly medial until the L4-5 zygapophyseal joint could be identified. Lumbar multifidus thickness measurements were made between the posterior-most portion of the L4-5 zygapophyseal joint and the plane between the muscle and subcutaneous tissue (Figure 1). Images of the lumbar multifidus were obtained at rest and during a submaximal contraction that consisted of a contralateral arm lift.[23] The contralateral arm lift was performed by lifting the arm approximately 5 cm off the plinth with the elbows flexed 90° and shoulders abducted 120° while the participant held a hand weight based on body mass.[23]

Images of the rectus abdominis were obtained with the participant supine. The inferior border of the transducer was placed immediately above the umbilicus and moved laterally from the midline until the muscle cross section was centered on the image. If required, a standoff pad was used to ensure that the entire cross-sectional area of the rectus abdominis was visualized within the field of view. Measurements of muscle thickness and cross-sectional area were obtained at rest (Figure 2). Electronic on-screen calipers were aligned at the muscle belly's center and measured from the inferior hyperechoic fascial line of the superficial border of the rectus abdominis to the superior hyperechoic fascial line of the inferior border of the rectus abdominis muscle; the cross-sectional area was obtained by tracing the interior border of the hyperechoic fascial line.[41]

Figure 1. Longitudinal view of the lumbar multifidus using a split-screen facility. The lumbar multifidus is imaged at rest (left) and during a contralateral arm raise (right). Thickness measurements were made between the posterior most portion of the L4-5 facet joint (F) and the plane between the muscle and subcutaneous tissue.
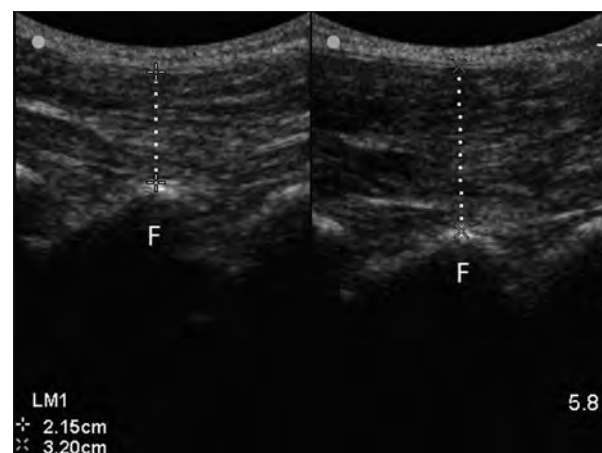
Images of the transversus abdominis and internal oblique muscles were acquired at rest and during the active straight leg raise maneuver.[42–44] Ultrasound images were obtained with the transducer positioned on the anterolateral aspect of the abdominal wall, superior to the iliac crest and perpendicular to the midaxillary line.[7,29,36,45] All images were obtained with the middle of the muscle belly centered within the field of view and at the end of a normal exhalation to control for the influence of respiration.[30]

The active straight leg raise maneuver was selected to assess automatic changes in the thickness of the lateral abdominal muscles during a lower extremity task while allowing for comparison with prior publications.[7,29] The active straight leg raise maneuver was performed with the participants positioned supine with arms resting across their chest, hips and knees extended, and heels placed 20 cm apart. During the active straight leg raise maneuver, the participant is asked to lift the lower extremity 5 cm off the plinth without bending the knee.[7] Images were obtained before lifting the lower extremity while the participant was at rest and after the lower extremity was lifted. Three trials were obtained.

All images were saved, and measurements of lateral abdominal muscle thickness were performed using Image-Pro Plus version 4.5 software (Image Processing Solutions, Inc, Silver Spring, MD). For a sample of 10 participants, 3 measurement techniques were used to assess muscle thickness (Table 1). Technique A consisted of using a single measurement between the superficial and deep borders of the muscle, as visualized by the hyperechoic fascial lines (Figure 3).[7,29,30,36,41] Technique B consisted of an average of 3 measurements of muscle thickness: the middle of the image and 1 cm to each side from midline (Figure 4).[9,46] The final measurement technique (technique C) consisted of outlining the superior and deep borders of the muscles across the 2-cm segment of the muscle belly, as outlined in technique B (Figure 5). The mean horizontal difference between those 2 lines represented the muscle thickness value. On the basis of these results, the entire sample of 21 participants was analyzed using technique B (see "Results" and "Discussion" sections).

Data Analysis

The dependent measures for the transversus abdominis, internal oblique, and lumbar multifidus muscles consisted of thickness values at rest and while contracted. The dependent measures for the rectus abdominis muscle consisted of thickness and cross-sectional area values at rest. An average of 3 measurements was used as the measurement of interest.[31] Inter-rater reliability was calculated using the ICC (1, 3) with 95% confidence intervals. Reliability values above 0.75 were considered good, and those below 0.75 were considered poor to moderate.[32,47] To assess measurement precision, standard error of the measurement and minimal detectable change values were calculated.[47] Data management and statistical analysis were performed using SPSS version 17.0 (SPSS Inc, Chicago, IL).

Figure 2. Cross-sectional scans of the rectus abdominis muscle. **A**, Measurements of muscle thickness were obtained between the deep and superficial borders of the rectus abdominis muscle. **B**, Measurement of the cross-sectional area was obtained by tracing the interior border of the rectus abdominis muscle.

A

B
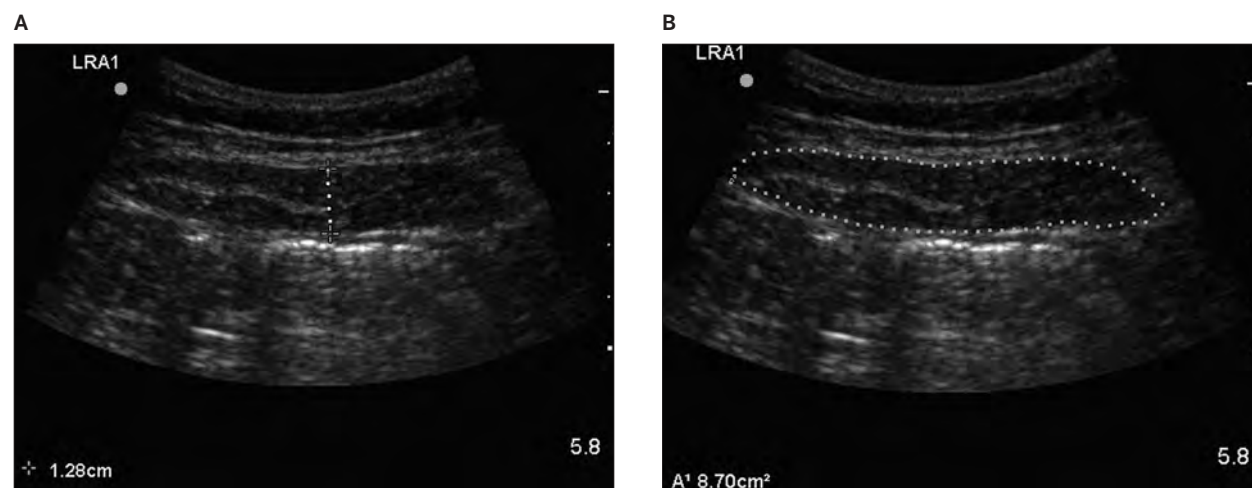
Results

Twenty-one participants (mean ± SD, 21.5 ± 4.4 years; 5 female and 16 male) completed the reliability study. Demographic and baseline characteristics of the participants are provided in Table 1. Inter-rater reliability of the 3 measurement techniques used to assess the lateral abdominal muscles is outlined in Table 2 (n = 10). All ICC values ranged from 0.80 to 0.92, while the standard error of the measurement ranged from 0.03 to 0.08 cm. The inter-rater reliability for each dependent measure is outlined in Table 3 (n = 21). All ICC values ranged from 0.86 to 0.94, and the standard error of the measurement ranged from 0.04 to 0.16 cm for the thickness values and 0.67 cm^2 for the cross-sectional area of the rectus abdominis muscle.
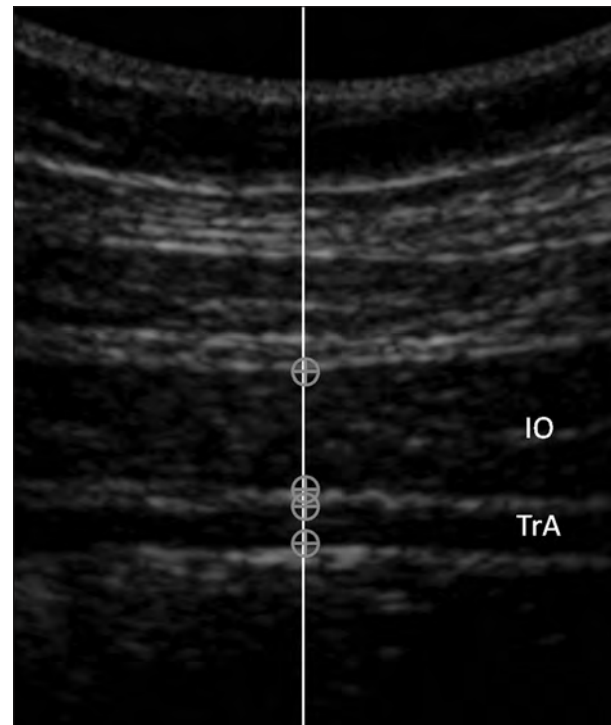
Discussion

The primary purpose of this study was to assess inter-rater reliability among different pairs of novice raters to obtain muscle thickness measurements at rest and during a submaximal contraction of the transversus abdominis, internal oblique, and lumbar multifidus muscles and measurements of the thickness and cross-sectional area of the rectus abdominis at rest. Overall, the ICC point estimates were greater than 0.85, indicating good to excellent reliability. These findings are consistent with the 2 previously published systematic reviews[32,33] and support our hypothesis that ultrasound imaging measurements are adequately reliable to assess muscle thickness. Previous researchers have demonstrated the importance of adequate rater training to obtain these measurements.[34,35] Although we did not directly assess the benefits of training, our findings do support the notion that even novice raters who complete a standardized training program can reliably obtain these measurements, which is in agreement with previously published reliability studies.[7,8,29,30,36,45] Although previous studies have assessed inter-rater reliability among novice raters,

Table 1. Demographic and Baseline Characteristics of the Participants (n = 21)

Characteristic	Value
Age, y	21.5 ± 4.4 (18–32)
Female, n (%)	5 (23.8)
Height, m	1.7 ± 0.1 (1.5–1.8)
Weight, kg	70.9 ± 8.7 (54.9–86.2)
Body mass index, kg/m^2	24.1 ± 3.1 (19.3–31.2)
No. of days exercise/wk	2.7 ± 1.1 (1–5)
No. of y consistently exercised	2.7 ± 1.5 (1–6)

Values are mean ± SD as applicable.

studies have been limited to 2 raters.[29] Our results also add to the existing literature by demonstrating that inter-rater reliability remains consistent across a variety of rater pairs, which increases the generalizability of our findings.

Lumbar Multifidus

The inter-rater reliability of the lumbar multifidus at rest and during a submaximal test demonstrated ICC point estimates between 0.87 and 0.94, with standard error of the measurement values between 0.14 and 0.16 cm and minimal detectable change values between 0.38 and 0.46 cm. The ICC values reported are slightly lower than some previously published values[27,34,48]; however, they are similar to those reported by Kiesel et al (ICC = 0.85).[23] The discrepancy in ICC point estimates may be related to methodological differences. Most of the previously published values assessed intra-rater reliability or allowed different raters to measure the same image. The standard error of the measurement values reported in this study are similar to those reported by Koppenhaver et al[29] and Van et al.[27] The minimal detectable change values only repre-

Figure 3. Transverse view of the lateral abdominal muscles: transversus abdominis (TrA) and internal oblique (IO). Measurements of muscle thickness were obtained by making a single measure of muscle thickness between the superficial and deep borders of the transversus abdominis and internal oblique muscles in the middle of the muscle belly.

sented 10% to 16% of the lumbar multifidus muscle thickness values, demonstrating better precision than the measurements obtained for the lateral abdominal muscles.

Abdominal Muscles

Although Rankin et al[41] previously reported that of all the abdominal muscles the rectus abdominis is the thickest muscle, limited information is available regarding the reliability of measuring the thickness and cross-sectional area of the rectus abdominis at rest. As would be expected, the values reported in this study are slightly lower than the intra-rater reliability values reported by Rankin et al[41] and are consistent with the other measures of reliability. As research continues to explore the changes in rectus abdominis musculature associated with pregnancy and its potential impact on low back pain,[49] further research to help standardize the measurement technique is indicated.

The inter-rater reliability of the transversus abdominis and internal oblique muscles at rest and while during the active straight leg raise maneuver demonstrated ICC point estimates between 0.86 and 0.93, with standard error of the measurement values between 0.04 to 0.07 cm and minimal detectable change values between 0.10 and 0.19 cm. These values are consistent with previously published values.[29,30,32,50] The standard error of the measurement for the transversus abdominis and internal oblique represents about 7% to 10% of the muscle thickness at rest or during the active straight leg raise maneuver. However, the minimal detectable change represents 20% to 25% of the mean muscle thickness values. Future research needs to investigate techniques to improve the precision of these measurements to adequately assess changes in muscle thickness values over time.

Measurement Technique for the Lateral Abdominal Muscles

Koppenhaver et al[29] demonstrated that more measurement error was attributed to image acquisition when compared to digital measurements of muscle thickness. This is hypothesized to be largely influenced by the variability in

Figure 4. Transverse view of the lateral abdominal muscles: transversus abdominis (TrA) and internal oblique (IO). Measurements of muscle thickness were obtained as an average of 3 measures of muscle thickness: the middle of the muscle belly and 1 cm to each side from midline. All measurements were obtained between the superficial and deep borders of the transversus abdominis and internal oblique muscles.
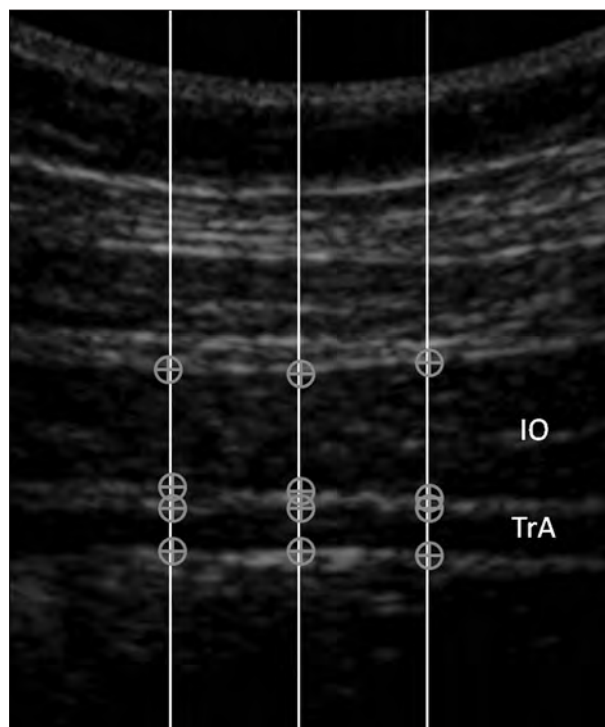
Figure 5. Transverse view of the lateral abdominal muscles: transversus abdominis (TrA) and internal oblique (IO). The superficial and deep borders of the transversus abdominis and internal oblique muscles were outlined. Measurements of muscle thickness were obtained by calculating the average distance between the hyperechoic borders of these muscles.
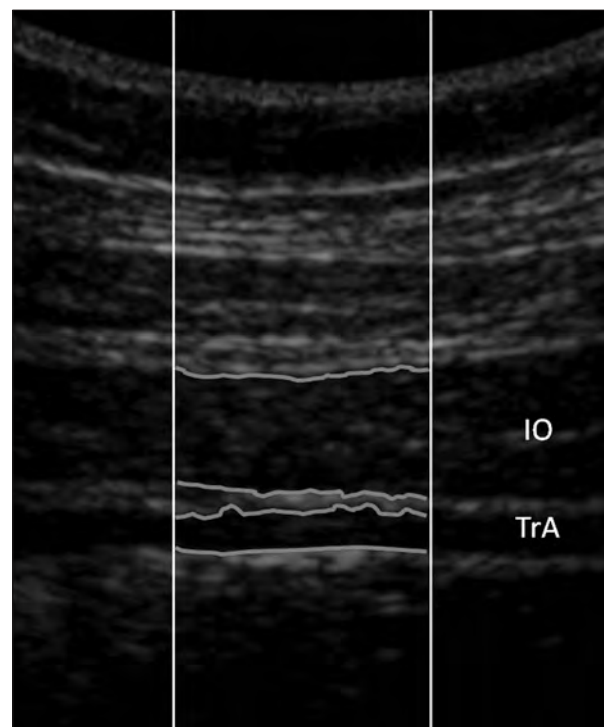
Table 2. Inter-Rater Reliability Comparing 3 Measurement Techniques for the Lateral Abdominal Muscle (n = 10)

Muscle (State)	Mean ± SD, cm	ICC (1, 3) (95% CI)	SEM, cm	MDC, cm
Transversus abdominis (rest)				
Technique A	0.42 ± 0.12	0.92 (0.71–0.98)	0.03	0.09
Technique B	0.42 ± 0.10	0.90 (0.63–0.98)	0.03	0.09
Technique C	0.42 ± 0.10	0.83 (0.33–0.96)	0.04	0.11
Transversus abdominis (ASLR)				
Technique A	0.47 ± 0.13	0.82 (0.29–0.96)	0.06	0.15
Technique B	0.47 ± 0.11	0.83 (0.35–0.96)	0.05	0.13
Technique C	0.46 ± 0.10	0.87 (0.46–0.97)	0.04	0.10
Internal oblique (rest)				
Technique A	1.00 ± 0.14	0.89 (0.58–0.97)	0.05	0.13
Technique B	0.99 ± 0.13	0.91 (0.64–0.98)	0.04	0.11
Technique C	1.01 ± 0.14	0.90 (0.61–0.97)	0.05	0.13
Internal oblique (ASLR)				
Technique A	1.08 ± 0.19	0.87 (0.48-0.97)	0.07	0.19
Technique B	1.08 ± 0.19	0.80 (0.16-0.95)	0.08	0.23
Technique C	1.10 ± 0.20	0.86 (0.43-0.97)	0.08	0.21

ASLR indicates active straight leg raise; CI, confidence interval; ICC, intraclass correlation coefficient; MDC, minimal detectable change; and SEM, standard error of the measurement. Technique A, single measure obtained at the center of the muscle belly; technique B, 3 measures of muscle thickness obtained at the center of the muscle belly and 1 cm medial and lateral to the center; and technique C, average distance between the inferior and superior fascial borders over the 2-cm segment outlined in technique B.

transducer placement on the body, pressure used by the examiner to maintain skin contact, and the transducer's angulation.[17] However, scant evidence exists to determine whether different techniques used for digital measurement could influence inter-rater reliability. Therefore, the secondary purpose of this study was to determine the optimal measurement technique for assessing lateral abdominal muscle thickness. The most common technique is to use a single measurement recorded as the distance between the superficial and deep borders in the middle of the muscle belly (technique A), as visualized by the hyperechoic fas-

cial lines (Figure 3).[7,29,30,36,41] However, variations in placement of the transducer and the measurement line could negatively affect reliability when measurements are obtained over time. Therefore, techniques that average multiple measures of muscle thickness have been proposed to improve reliability. This study compared 2 additional techniques to measure muscle thickness. Technique B consisted of an average of 3 measures of muscle thickness across a 2-cm segment of the muscle (Figure 4),[9,46] whereas technique C represented the mean distance between the superior and deep borders of the muscles across

Table 3. Inter-Rater Reliability (n = 21)

Muscle and State	Mean ± SD, cm	ICC (1, 3) (95% CI)	SEM	MDC
Rectus abdominis				
Thickness, cm	1.33 ± 0.22	0.91 (0.79–0.96)	0.07	0.22
CSA, cm^2	7.18 ± 1.79	0.86 (0.65–0.94)	0.67	1.85
Transversus abdominis				
Rest, cm	0.41 ± 0.10	0.86 (0.65–0.94)	0.04	0.10
ASLR, cm	0.45 ± 0.11	0.87 (0.67–0.95)	0.04	0.11
Internal oblique				
Rest, cm	0.93 ± 0.23	0.91 (0.77–0.96)	0.07	0.19
ASLR, cm	1.00 ± 0.26	0.93 (0.82–0.97)	0.07	0.19
Lumbar multifidus				
Rest, cm	2.83 ± 0.46	0.87 (0.68–0.95)	0.16	0.46
Contracted, cm	3.50 ± 0.56	0.94 (0.86–0.98)	0.14	0.38

ASLR indicates active straight leg raise; CI, confidence interval; CSA, cross-sectional area; ICC, intraclass correlation coefficient; MDC, minimal detectable change; and SEM, standard error of the measurement.

the 2-cm segment of the muscle belly (Figure 5). The differences between the measurement techniques were negligible, and no single technique demonstrated a consistent pattern of improved reliability compared to the other techniques. However, the technique requiring the rater to outline the superior and inferior borders of the fascial lines over the 2-cm segment of muscle (technique C) is more time-consuming and therefore less clinically feasible compared to techniques A and B. On the basis of these results, it appears that a single measure of muscle thickness in the center of the muscle belly is equivalent to obtaining the average of 3 measures of muscle thickness over a 2-cm region of the muscle belly. Theoretically, the latter technique in which an average measure of muscle thickness over a 2-cm segment of the muscle is obtained may be more robust for analyzing changes in muscle morphology over time. Further research is warranted to establish whether this is the case.

Several limitations existed within this study. In line with the ultimate goal of the prevention of low back pain in the military trial,[37] this study was conducted in healthy adults without low back pain. Despite being conducted on those without abnormalities, the results are similar to those with low back pain.[29] However, further research is needed to assess the generalizability of these findings to those with more chronic low back pain and geriatric populations. The inter-rater reliability assessed in this study was conducted within the same session. The influence of larger time intervals on reliability needs to be assessed.[32,33] A larger sample may have resulted in smaller confidence intervals around the point estimates of the ICC values. Finally, the reliability calculated in this study was based on an average of 3 measures. This is based on variations in muscle recruitment during submaximal tasks and prior research demonstrating the improved reliability.[29–31,34]

In conclusion, thickness measures of the transversus abdominis, internal oblique, and lumbar multifidus muscles obtained with ultrasound imaging at rest and during submaximal contractions demonstrate good to excellent reliability. Moreover, the results appear to be generalizable to novice raters who receive a standardized training program before obtaining measurements. Given good to excellent reliability, these results support the potential use of ultrasound imaging measurements for management decisions in the diagnosis and treatment motor control impairments. Further research is needed to determine whether the use of ultrasound imaging in the patient care process translates into improved outcomes.

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Effects of Traditional Sit-up Training Versus Core Stabilization Exercises on Short-Term Musculoskeletal Injuries in US Army Soldiers: A Cluster Randomized Trial

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Background. The US Army has traditionally utilized bent-knee sit-ups as part of physical training and testing. It is unknown whether the short-term effects of a core stabilization exercise program without sit-up training may result in decreased musculoskeletal injury incidence and work restriction compared with traditional training.

Objective. The objective of this study was to explore the short-term effects of a core stabilization exercise program (CSEP) without sit-up training and a traditional exercise program (TEP) on musculoskeletal injury incidence and work restriction.

Design. The study was designed as a cluster randomized trial.

Setting. The setting was a 16-week training program at Fort Sam Houston (San Antonio, Texas).

Participants. The study participants were soldiers with a mean age of 22.9 years (SD=4,7, range=18–35) for whom complete injury data were available for analysis (n=1,141).

Intervention. Twenty companies of soldiers were cluster randomized to complete the CSEP (10 companies of 542 soldiers) or the TEP (10 companies of 599 soldiers). The CSEP included exercises targeting the transversus abdominus and multifidus musculature. The TEP comprised exercises targeting the rectus abdominus, oblique abdominal, and hip flexor musculature.

Measurements. Research staff recorded all injuries resulting in the inability to complete full duty responsibilities. Differences in the percentages of musculoskeletal injuries were examined with chi-square analysis; independent sample *t* tests were used to examine differences in the numbers of days of work restriction.

Results. Of the 1,141 soldiers for whom complete injury data were available for analysis, 511 (44.8%) experienced musculoskeletal injuries during training that resulted in work restrictions. There were no differences in the percentages of soldiers with musculoskeletal injuries. There also were no differences in the numbers of days of work restriction for musculoskeletal injuries overall or specific to the upper extremity. However, soldiers who completed the TEP and experienced a low back injury had more days of work restriction: 8.3 days (SD=14.5) for the TEP group and 4.2 days (SD=8.0) for the CSEP group.

Limitations. A limitation of this study was the inconsistent reporting of injuries during training. However, the rates of reporting were similar between the groups.

Conclusions. The incidences of musculoskeletal injuries were similar between the groups. There was marginal evidence that the CSEP resulted in fewer days of work restriction for low back injuries.

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Traditional Sit-up Training Versus Core Stabilization Exercises in Musculoskeletal Injuries

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The US Army has incorporated traditional bent-knee sit-ups (with the hands interlocked behind the head) during physical fitness training for many years.[1] Sit-ups test muscular endurance for the abdominal and hip flexor muscles and have validated normative standards based on sex and age.[1] This exercise has been adopted as part of the military's physical training doctrine because of its ease of testing groups of people and the notion that poorer performance of sit-ups on the Army Physical Fitness Test (APFT) has been associated with a higher incidence of musculoskeletal injuries.[2] Sit-ups also are commonly incorporated in general public training routines for the purpose of improving abdominal and hip flexor muscular endurance.

Despite longstanding tradition and the widespread popularity of sit-ups, it has been postulated that this exercise results in increased lumbar spine loading, potentially increasing the risks of injury and low back pain (LBP). Specifically, sit-ups produce large shear and compressive forces on intervertebral disks and across the lumbar spine.[3-5] Increased muscle activation anteriorly results in both initial hyperextension and subsequent hyperflexion of the lumbar spine, contributing to large compressive forces during sit-ups.[6,7]

To address these potential concerns, health and fitness professionals commonly recommend alternative "core stabilization" exercises (also commonly known as "lumbar stabilization" or "motor control" exercises), which comprise abdominal and trunk muscle strengthening exercises, in lieu of sit-ups to improve abdominal muscular fitness.[8] These recommendations are based on the accumulated evidence demonstrating that these exercises selectively activate the key abdominal and trunk musculature (ie, the transversus abdomi-nus, multifidus, erector spinae, and quadratus lumborum muscles) involved in controlling forces across the lumbar spine.[9-13] This literature has demonstrated that these exercises should be prescribed because they are based on controlled-activation, low-load principles, which require minimal trunk movements that better match the function of the muscles and contribute to improved trunk neuromuscular control.[4,7] Advocates of these approaches also cite research indicating that abdominal crunch and trunk stabilization exercises optimize the challenge to the abdominal muscles while minimizing potentially deleterious lumbar spine forces.[3,14]

Core stabilization exercises have been supported by the US Army and advocated for inclusion in US Army physical fitness training programs[15]; however, US Army personnel are still required to take an APFT that incorporates a 2-minute maximal sit-up test. Failure to pass the APFT can have negative consequences on a soldier's career and decrease the chance for promotion; this may be one reason why a core stabilization exercise program (CSEP) has not been widely adopted in the US Army. However, Childs et al[16] recently found that a CSEP did not have a detrimental effect on sit-up performance or overall fitness scores or pass rates. There was a small but significantly greater increase in sit-up pass rates in a group receiving a CSEP (5.6%) than in a group receiving a traditional exercise program (TEP) (3.9%).[16]

Despite recent evidence that incorporating a CSEP into US Army physical training does not increase the risk of suboptimal performance on the APFT,[16] it is important to establish that any newly proposed training programs do not pose unintended consequences, such as an increased risk of musculoskeletal injuries dur-

ing training. As an example, there have been anecdotal concerns that the horizontal side support exercise (Fig. 1) might contribute to an increase in upper-extremity (UE) injuries because of the prolonged weight bearing through the shoulders that is associated with this exercise. Despite the hypothesized concerns, there are no empirical data indicating whether this exercise actually poses a real injury risk. From a broader health policy perspective, previous studies of soldiers in US Army basic training showed that the incidences of injuries during training varied from 23% to 28% for men and 42% to 67% for women.[17–21] Musculoskeletal injuries during training delay the successful completion of training or result in soldiers having to drop out of training; the end result is substantial lost productivity associated with costs estimated to be in the millions of dollars per year.[2,22–24] An adequate understanding of the potential injury risks associated with any newly proposed training programs is essential to inform policy decision making.

Therefore, the purpose of this study was to explore the short-term effects of a CSEP and a TEP on musculoskeletal injury incidence and work restriction. We hypothesized that there would be no differences between the groups in short-term injury incidence or work restriction. Advancing the understanding of the implications of newly proposed training regimens for short- and long-term injury rates will aid in policy decision making related to the design and implementation of optimal physical training guidelines in the military.

Method
Design Overview
Consecutive soldiers entering a 16-week training program at Fort Sam Houston, San Antonio, Texas, to become combat medics in the US Army

Figure 1.
Horizontal side support exercise, part of the core stabilization exercise program.

were considered for study participation. This study is a report of a planned analysis of the proximal outcome of a clinical trial concerning the prevention of LBP in the military (NCT00373009),[25] which has been registered at http://clinicaltrials.gov.

In the primary trial, soldiers were randomized in clusters to receive a CSEP alone, a CSEP with a psychosocial education program, a TEP, or a TEP with a psychosocial education program. Soldiers are currently being monitored monthly for 2 years after the completion of training to assess the long-term outcomes regarding LBP occurrence and severity. However, the results of the primary trial are not yet available. Because the educational program was not designed to affect injury rates, we collapsed the study population into 2 groups (TEP group and CSEP group) for the purpose of this analysis.

Setting and Participants
Research staff at Fort Sam Houston introduced the study to individual companies of soldiers and obtained written informed consent. Soldiers were recruited during a training orientation session attended by all soldiers as part of their preparation for medic training. For 8 consecutive

months, soldiers were screened for eligibility according to the inclusion and exclusion criteria. Soldiers were required to be 18 to 35 years of age (or 17-year-old emancipated minors), participating in training to become combat medics, and able to speak and read English. Soldiers with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the soldier to seek health care. Soldiers also were excluded if they were currently seeking medical care for LBP; were unable to participate in unit exercise because of an injury in the foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand; had a history of fracture (stress or traumatic) in the proximal femur, hip, or pelvis; were pregnant; or had been transferred from another training group. Other possible reasons for exclusion included acceleration into a company that had already been randomized and recruited for participation in the clinical trial concerning the prevention of LBP in the military or reassignment to an occupational specialty other than combat medic.

Figure 2 shows a flow diagram describing the numbers of companies
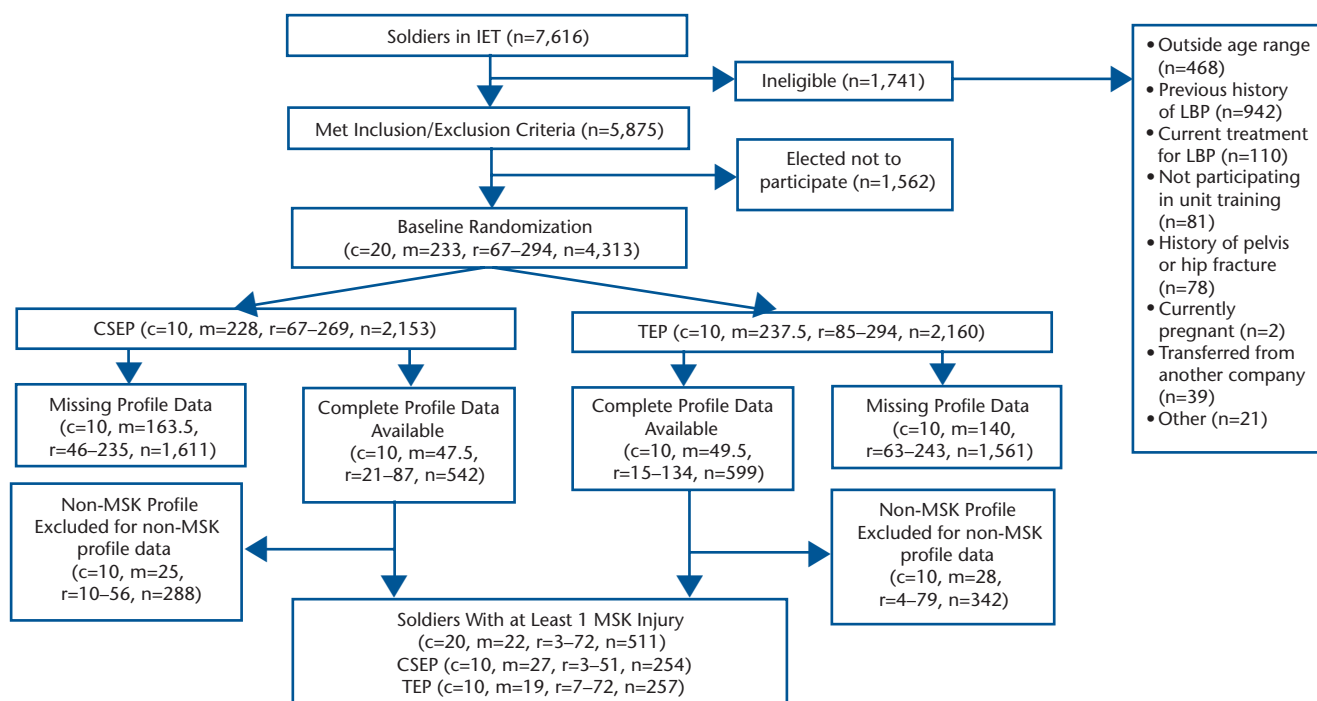
Figure 2.
Flow diagram for participant recruitment and randomization. c=number of companies, CSEP=core stabilization exercise program, IET=initial entry training, LBP=low back pain, m=median company size (number of soldiers), MSK=musculoskeletal, n=total number of soldiers, r=range of company size (number of soldiers), TEP=traditional exercise program.

and soldiers who were considered for the clinical trial, who were eventually enrolled in the trial, and who completed the follow-up assessment, in accordance with the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement.[26,27]

Randomization and Interventions

Military training environments require living in close quarters with other members of the unit, making individual randomization not feasible for this trial because of concerns related to the disruption of the normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was used for assigning companies to receive a TEP or a CSEP. This meant that for a given company, every soldier who consented to the study received the same study condition. Cluster randomization is a viable methodologi-

cal choice that has been effectively used in other large samples of primary prevention.[28-30] The randomization schedule was prepared by computer before recruitment began and was balanced to ensure equal allocation to both conditions after 20 companies were recruited.

Soldiers in both groups performed the assigned exercise programs in a group setting under the direct supervision of their drill instructors as part of daily unit physical training. The exercise regimens for both groups consisted of 5 or 6 exercises, each of which was performed for 1 minute. Exercise programs were performed daily, for a total dosage time of approximately 5 minutes per day, 4 days per week, over a period of 12 weeks. Performing the exercise programs under the supervision of drill instructors and in a group setting helped to ensure compliance with the assigned program and dos-

age. Other aspects of standard physical training (ie, warm-up, aerobic training, strength and conditioning drills, and cool-down) were performed to US Army standards by both groups. Additional details regarding each exercise program are given elsewhere.[16]

The soldiers' drill instructors were given comprehensive training in the study procedures by the research staff before the initiation of the study. The drill instructors were given detailed training cards specific to each program. This information also was provided to the drill instructors on the Web site for the primary trial (http://polm.ufl.edu) for reference purposes. This training ensured that both the drill instructors and the soldiers were proficient in their assigned exercise programs and enhanced their ability to accomplish the exercise programs in a standardized manner. Study personnel super-

vised physical training for an average of 2 days per week over the 12-week training period to answer questions and monitor adherence to the assigned exercise programs.

Outcomes and Follow-up

Study-related measures were collected before training and 12 weeks later, when training was completed, by study personnel who were unaware of the randomization assignments. All measures were scored in a masked manner by computer algorithm. Soldiers provided standard demographic information, such as age, sex, and past medical history, and completed a variety of health outcome measures. It was not possible to prevent soldiers from being aware of their group assignments because they actively participated in their randomly assigned training programs. However, APFT scores were collected by drill instructors according to the standard testing procedures outlined below.[1] The drill instructors were not formally involved with the study other than within the context of the usual training environment.

As part of the primary trial, research staff aggregated the data on all injuries (musculoskeletal and nonmusculoskeletal) resulting in work restrictions on the basis of information provided by the administrative clerks within the soldiers' units. A *work restriction* was defined as any restriction that resulted in a soldier's inability to complete full duty responsibilities. The administrative clerks recorded injuries resulting in work restrictions on Department of the Army Form 3349 (Physical Profile) according to the US Army's standard reporting procedures. Physical profiling is a system of classifying people according to functional abilities.[31] A profile identifies a soldier's medical condition and functional activity limitations and makes suggestions for accommodative work

environments and necessary work restrictions for a specified period of time. Physical profiles are issued by health care providers upon evaluation of a soldier's physical status immediately after an injury is reported. Profiles were collected on a weekly basis by study personnel.

Injuries were first classified as being musculoskeletal or nonmusculoskeletal in origin. Musculoskeletal injuries were injuries that affected the musculoskeletal system and that might have been associated with exercise and military training. Traumatic injuries (eg, a femur fracture) that could not possibly be related to the training regimen were excluded. An example of a nonmusculoskeletal injury would be a condition such as the common cold. Musculoskeletal injuries were further classified according to key body regions of interest (low back, UE, and lower extremity [LE]). We did not report separately the number of neck-related injuries because there was no hypothesis about the potential of a TEP or a CSEP to adversely affect the cervical spine. Low back injuries were defined as those affecting the lumbopelvic region. Upper-extremity injuries were defined as injuries affecting the shoulder, elbow, wrist, or hand. Lower-extremity injuries were defined as injuries affecting the hip, knee, ankle, or foot. In the event an injury crossed over regions (such as low back and hip pain), the injury was classified according to the location of the primary pain. The incidence of injury was determined by counting the number of profiles for each type of injury during training. The duration of injury was recorded as the number of days of work restriction, as annotated on the Physical Profile form.

Data Analysis

Descriptive statistics, including measures of central tendency and dispersion for continuous variables, were

calculated to summarize the data. The demographic and baseline levels of variables were compared between the groups (ignoring clusters) by use of t tests for comparison of means and chi-square tests for comparison of proportions.

The exercise groups (CSEP and TEP) were compared for musculoskeletal injury incidence overall and according to body region (low back, UE, and LE) and for *work restriction*, defined as the number of days of work restriction. Differences in the percentages of musculoskeletal injuries were examined by use of hierarchical logistic regression; differences in the number of injuries and the number of days of work restriction were analyzed by use of hierarchical Poisson regression. The GLIMMIX procedure was used for the analyses, including a random company effect to model the correlations within clusters. The alpha level was set to .05 *a priori*. Soldiers with missing data were excluded because the purpose of this study was to determine the impact of a CSEP among soldiers who completed the full training period. All statistical analyses were performed with SAS version 9.1.*

Results

Twenty companies with a total of 7,616 soldiers were screened for inclusion in the study. Of these soldiers, 5,875 were eligible to participate. Reasons for ineligibility included being outside the age range (n=468); having a history of LBP

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* SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.

Table 1.
Demographic and Other Baseline Variables[a]

Variable	All	CSEP Group	TEP Group	P
No. of companies	20	10	10	
No. of soldiers	1,141	542	599	
Age, y, $\overline{X}$ (SD)	22.7 (4.6)	22.5 (4.5)	22.7 (4.7)	.745
Sex (% men)	60.9	60.1	61.6	.615
Body mass index, kg/m², $\overline{X}$ (SD)	24.9 (3.6)	24.8 (3.2)	24.9 (3.9)	.538
Receiving PSEP (%)	51.6	50.0	53.1	.297
Complete profile data available (%)	26.4	25.2	27.7	.059
Currently smoke (%)	41.2	42.1	41.6	.776
Previous routine exercise (%)	42.7	47.2	44.9	.127
Education, some college (%)	56.3	56.6	55.9	.808
Previous profile (%)[b]	32.4	33.0	32.7	.818

[a] CSEP=core stabilization exercise program, TEP=traditional exercise program, PSEP=psychosocial education program that was part of the larger clinical trial.
[b] The percentage of individuals who were issued a physical profile for an injury or illness prior to arriving for the 16-week training program at Fort Sam Houston.

(n=942); currently seeking care for LBP (n=110); not participating in unit physical training (n=81); having a history of pelvis or hip fracture (n=78); currently being pregnant (n=2); transfer from another company (n=39); and other, unspecified reasons (n=21). Of the eligible soldiers, 4,313 (73.4%) consented to participate. Complete profile data were available for 1,141 (27.7%) of the randomized soldiers because of inconsistent reporting of profiles (Fig. 2); however, the rates of reporting were similar between the groups (Tab. 1).

The mean age of the soldiers was 22.7 years (SD=4.6 years), and 60.9% were men (Tab. 1). The demographic variables were similar between the exercise groups (Tab. 1). Of the 1,141 soldiers for whom complete profile data were available, 511 (44.8%) experienced at least 1 musculoskeletal injury (254 in the CSEP group and 257 in the TEP group). There were no statistically significant differences in the percentages of soldiers with musculoskeletal injuries overall (42.9% in the TEP group and 46.9% in the CSEP group; P=.757) or according to

body region: 11.0% in the TEP group and 13.3% in the CSEP group (P=.283) for LB, 30.7% in the TEP group and 31.5% in the CSEP group (P=.852) for LE, and 4.5% in the TEP group and 6.1% in the CSEP group (P=.513) for UE (Tab. 2). Among soldiers with at least 1 musculoskeletal injury (n=511), there were no differences in the incidence of musculoskeletal injuries overall or according to body region (P>.05); the average soldier experienced 1.2 injuries during training, and the majority of these injuries were LE injuries (0.8 LE injury per soldier during training) (Tab. 3). Additionally, there were no statistically significant differences in the number of days of work restriction for musculoskeletal injuries overall or specific to the LE or UE. Means (SD) for musculoskeletal injuries overall were 21.4 (24.7) days in the TEP group and 20.4 (16.9) days in the CSEP group (P=.919), those for musculoskeletal injuries specific to the LE were 20.0 (23.8) days in the TEP group and 19.5 (15.6) days in the CSEP group (P=.791), and those for musculoskeletal injuries specific to the UE were 19.5 (17.0) days in the TEP group and 24.0 (23.1) days in the CSEP group (P=.634). Soldiers who were in the TEP group and who experienced a low back injury did experience more days of work restriction; means (SD) were 8.3 (14.5)

Table 2.
Musculoskeletal Injuries That Resulted in Work Restrictions Among Soldiers (n=1,141)

Type of Injury	CSEP Group[a]			TEP Group[b]			
	No. of Soldiers	% of Soldiers	Range of Cluster Percentages	No. of Soldiers	% of Soldiers	Range of Cluster Percentages	P
Musculoskeletal (any)	254	46.9	14.3–63.8	257	42.9	16.7–73.3	.757
Low back	72	13.3	0–22.7	66	11.0	5.6–19.2	.283
Lower extremity	171	31.5	8.8–50	184	30.7	7.4–53.3	.851
Upper extremity	33	6.1	0–19.6	27	4.5	0–10.0	.513

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 542 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 599 soldiers.

Table 3.
Number of Injuries That Resulted in Work Restrictions in Soldiers With at Least 1 Musculoskeletal Injury (n=511)

Type of Injury	CSEP Group[a]			TEP Group[b]			
	No. of Injuries		Range of Cluster Averages	No. of Injuries		Range of Cluster Averages	P
	X̄	SD		X̄	SD		
Musculoskeletal (any)	1.3	0.5	1.0–1.6	1.2	0.5	1.0–1.4	.699
Low back	0.3	0.6	0–0.5	0.3	0.5	0.2–0.5	.616
Lower extremity	0.8	0.6	0.5–1.1	0.8	0.6	0.4–1.0	.809
Upper extremity	0.1	0.3	0–0.3	0.1	0.3	0–0.2	.888

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 254 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 257 soldiers.

days in the TEP group and 4.2 (8.0) days in the CSEP group (P=.083) (Tab. 4).

Discussion

The results of the present study indicate that a CSEP does not result in increased incidence or duration of musculoskeletal injuries during training. Furthermore, the data refute anecdotal concerns that have been raised regarding the horizontal side support exercise (Fig. 1) in a CSEP increasing the potential to experience a UE injury. Approximately 5% of all injuries (musculoskeletal and nonmusculoskeletal) during training were UE injuries; however, there were no differences in UE injury rates between the groups (Tab. 2). The most common injuries were LE injuries, which accounted for more than 30% of all injuries, followed by low back injuries (12%) (Tab. 2). These data confirm those of pre-

vious studies demonstrating that low back and LE injuries are the most common injuries experienced during training.[2,24]

Soldiers with UE and LE injuries experienced similar numbers of days of work restriction regardless of exercise group (20–24 days) (P>.05) (Tab. 4); however, soldiers who experienced a low back injury did experience more days of work restriction with the TEP than with the CSEP: 8.3 (14.5) days and 4.2 (8.0) days, respectively (P=.083) (Tab. 4). Although this finding is not statistically significant, a potentially relevant effect may be emerging, as demonstrated by a between-group effect size of .37. Given the evidence from the biomechanical literature demonstrating that sit-ups produce large shear and compressive forces on intervertebral disks and across the lumbar spine,[3–5] perhaps the trend to-

ward a short-term increase in the number of days of work restriction in association with the TEP is attributable to these suboptimal biomechanical effects. Another possibility is that the increase in the number of days of work restriction indicates an early protective benefit of the CSEP with respect to low back injuries. However, in light of the marginal P value, combined with the fact that we would not expect to detect a difference in work restriction in response to the CSEP over such a short period of time, this interpretation should be viewed with caution. Whether the CSEP is protective against the development of low back injuries will be established more definitively once the 2-year follow-up is complete.

One of the potential limitations of the present study was the inconsistent reporting of injuries during

Table 4.
Number of Limited-Duty Days That Resulted in Work Restrictions in Soldiers With at Least 1 Musculoskeletal Injury

Type of Injury	CSEP Group[a]			TEP Group[b]			
	No. of Days		Range of Cluster Averages	No. of Days		Range of Cluster Averages	P
	X̄	SD		X̄	SD		
Musculoskeletal (any)	20.4	16.9	14.1–28.8	21.4	24.7	10.6–28.5	.919
Low back	4.2	8.0	0–5.8	8.3	14.5	0–18.2	.083
Lower extremity	19.5	15.6	15.4–28.0	20.0	23.8	8.8–26.6	.791
Upper extremity	24.0	23.1	7.0–33.2	19.5	17.0	0–44.5	.634

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 254 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 257 soldiers.

training; therefore, the absolute number of injuries reported during training likely was underestimated. However, the rates of reporting were equally represented across the groups (Tab. 1). Another potential limitation is that although we excluded soldiers with a current or a previous history of LBP or other injuries that would interfere with the successful completion of unit physical training, we did not control for previous non–low back musculoskeletal injuries, except those that would interfere with the completion of unit physical training. However, because we excluded soldiers with any previous low back injuries and soldiers with non–low back musculoskeletal injuries that would interfere with the successful completion of unit physical training, it is unlikely that a previous history of nonserious musculoskeletal injuries would have contributed to current injury complaints during training.

Despite evidence from the biomechanical literature supporting the potential benefits of a CSEP as well as current literature illustrating that a CSEP does not result in decreased performance on the APFT,[16] more definitive research on the potential long-term protective effects of a CSEP on injury rates is needed. We propose that future research consider the potential of a CSEP to prevent musculoskeletal injuries, such as LE and low back injuries, in the long term. We also propose conducting a similar study outside military training environments to determine whether the results can translate to the general population.

These early data provide confidence that a long-term study of a CSEP in military training environments can be successfully carried out without increasing the risks of musculoskeletal injuries or decrements in fitness test scores, as previously reported.[16] These data, in addition to the long-term results of the primary trial, will

assist health care professionals and policy makers in designing optimal military physical training programs that best maintain optimal physical fitness, maximize performance, and minimize potential injuries in both the short term and the long term. There also may be applications for clinicians, who could recommend these exercises as part of wellness or fitness routines.

Conclusions

The results of the present study demonstrated that the CSEP did not increase the incidence of musculoskeletal injuries or days of work restriction during training, regardless of the involved body region. In fact, the TEP resulted in approximately 4 more days of work restriction than the CSEP. These results may be explained by the increased shear and compressive forces across the lumbar spine during sit-ups[3-5] or may attest to an early protective effect of the CSEP. Future research should aim to determine whether the CSEP has long-term protective effects on common musculoskeletal injuries, such as LE and low back injuries.

Dr Childs, Dr Teyhen, and Dr George provided concept/idea/research design and fund procurement. Dr Childs, Dr Teyhen, Mr Casey, Ms McCoy, Ms Feldtmann, Dr Wu, and Dr George provided writing. Dr Childs, Dr Teyhen, Mr Casey, Ms McCoy, Ms Feldtmann, Ms Wright, and Ms Dugan provided data collection. Dr Childs, Dr Teyhen, Mr Casey, Ms McCoy, Ms Feldtmann, and Dr Wu provided data analysis. Dr Childs, Dr Teyhen, Ms Wright, and Ms Dugan provided project management. Dr Childs and Dr Teyhen provided participants. Dr Childs and Dr Teyhen provided facilities/equipment and institutional liaisons. Dr Childs, Dr Teyhen, Ms McCoy, Ms Feldtmann, Ms Wright, Ms Dugan, and Dr George provided consultation (including review of manuscript before submission). We thank Christopher Barnes, Yang Li, and Erik Henrickson for the creation and management of the Web site and database and Donna Cunningham for administrative assistance. We are grateful to various students within the physical therapy pro-

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Effects of Sit-up Training versus Core Stabilization Exercises on Sit-up Performance

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ABSTRACT

CHILDS, J. D., D. S. TEYHEN, T. M. BENEDICT, J. B. MORRIS, A. D. FORTENBERRY, R. M. MCQUEEN, J. B. PRESTON, A. C. WRIGHT, J. L. DUGAN, and S. Z. GEORGE. Effects of Sit-up Training versus Core Stabilization Exercises on Sit-up Performance. *Med. Sci. Sports Exerc.*, Vol. 41, No. 11, pp. 2072–2083, 2009. **Purpose**: Core stabilization exercises target abdominal and trunk muscles without the excessive loading that occurs during sit-ups. However, core stabilization exercise programs (CSEP) have not been widely adopted in the US Army partially because of the perceived deleterious impact they would have on performance during the Army Physical Fitness Test. The purpose was to determine whether performing CSEP in lieu of sit-ups during unit physical training would have detrimental effects on sit-up performance and passing rates on the fitness test. **Methods**: Soldiers ($N = 2616$) between 18 and 35 yr of age were randomized to receive a traditional exercise program (TEP) with sit-ups or CSEP. Subjects with a previous history of low back pain or other injury precluding participation in training were excluded. The training programs were completed four times per week for 12 wk. Performance was assessed at baseline and after 12 wk. **Results**: Both groups demonstrated significant improvements in sit-up performance and overall fitness scores over time ($P < 0.001$). There were no significant between-group differences in overall fitness scores ($P = 0.142$) or sit-up performance ($P = 0.543$). However, CSEP resulted in a significant improvement in sit-up passing rates by 5.6% compared with 3.9% for the TEP group ($P = 0.004$). **Conclusions**: CSEP did not have a detrimental impact on sit-up performance or overall fitness scores or pass rates. There was a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP group (3.9%). Incorporating CSEP into Army physical training does not increase the risk of suboptimal performance on the Army's fitness test and may offer a small benefit for improving sit-up performance. **Key Words**: FITNESS, LOW BACK PAIN, LUMBAR SPINE, PREVENTION, MILITARY

The US Army has incorporated traditional bent-knee sit-ups (with the hands interlocked behind the head) during physical fitness training for many years (2). Sit-ups test muscular endurance for the abdominal and hip flexor muscles and have validated normative standards on the basis of sex and age (2). This exercise has been adopted as part of the military's physical training doctrine on the basis of its ease of testing groups of individuals and on the basis of the notion that lower performance of sit-ups on the Army Physical Fitness Test (APFT) has been associated with a higher incidence of musculoskeletal injuries (13).

Sit-ups are also commonly incorporated in general public training routines for the purpose of improving abdominal and hip flexor muscular endurance.

Despite long-standing tradition and widespread popularity of performing sit-ups, it has been postulated that this exercise results in increased lumbar spine loading, potentially increasing the risk of injury and low back pain (LBP). Specifically, sit-ups produce large shear and compressive forces on the intervertebral disc and across the lumbar spine (4,15,18). Increased muscle activation anteriorly during the sit-up results in both an initial hyperextension and a subsequent hyperflexion of the lumbar spine, contributing to high compressive forces of the lumbar spine (19,22).

To address these potential concerns, health and fitness professionals commonly recommend performing alternative "core stabilization" exercises, which are composed of abdominal and trunk muscle strengthening exercises in lieu of sit-ups to improve abdominal muscular fitness (1). These recommendations are based on the accumulated evidence demonstrating that these exercises selectively activate key abdominal and trunk musculature (i.e., transversus abdominis, multifidus, erector spinae, quadratus lumborum, etc.)

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involved in controlling forces across the lumbar spine (8–12,16). This literature has demonstrated that these exercises should be prescribed on the basis of controlled activation, low load principles that require minimal trunk movements, hence better matching the muscle's function and contributing to improved trunk neuromuscular control (16,23). Advocates of these approaches also point to research indicating that abdominal crunch and trunk stabilization exercises optimize the challenge to the abdominal muscles while minimizing potentially deleterious lumbar spine forces (4,7).

Core stabilization exercises have been supported by the US Army and advocated for inclusion into US Army physical fitness training programs (3); however, US Army personnel are still required to take an APFT that incorporates a 2-min maximal sit-up test. Failure to pass the APFT can have negative consequences on a soldier's career and decrease the chance for promotion; hence, this may be one reason why core stabilization exercise programs (CSEP) have not been widely adopted in the US Army.

Despite the theoretical risk of suboptimal sit-up performance on the physical fitness test, scant empirical evidence is available to inform whether performing a CSEP in lieu of sit-ups is a valid concern. Baxter et al. (5) observed no decrement in sit-up performance among a small cohort of US Military Cadets at West Point who exclusively performed abdominal crunch exercises during a 6-wk training period. However, data demonstrating similar sit-up performance and overall fitness as measured by the APFT among subjects performing a CSEP could inform decision making regarding the development of optimal physical training and fitness assessment programs in the US military. In addition, these data could help inform the design of optimal fitness training programs for the public at large. Therefore, the purpose of this study was to determine whether performing CSEP in lieu of sit-ups during a 12-wk training period has detrimental effects on performance of sit-ups and overall fitness as measured by the APFT. We hypothesized that there would be no differences in APFT sit-up scores or overall passing rates on the basis of whether subjects performed a traditional exercise program (TEP) or CSEP.

METHODS

Consecutive subjects entering a 16-wk training program at Fort Sam Houston, TX, to become a combat medic in the US Army were considered for participation in this study. This study reports a planned analysis of a proximal outcome of the Prevention of Low Back Pain in the Military clinical trial (NCT00373009) (6), which has been registered at http://clinicaltrials.gov.

In the primary trial, subjects were randomized in clusters to receive CSEP alone, CSEP with a psychosocial education program, TEP, or TEP with a psychosocial education program. Subjects are currently being followed monthly for 2 yr after completion of training to assess the long-term outcomes of LBP occurrence and severity. However, the primary trial results are not yet available. Because the educational program was not designed to impact sit-up performance, we collapsed the study into two groups (TEP or CSEP) for the purpose of this analysis.

Subjects. Research staff at Fort Sam Houston, TX, introduced the study to individual companies of soldiers and obtained written informed consent. For eight consecutive months, subjects were screened for eligibility according to the inclusion/exclusion criteria. Subjects were required to be 18–35 yr of age (or 17-yr-old emancipated minor), participating in training to become a combat medic, and be able to speak and read English. Subjects with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 h, and caused the subject to seek health care. Subjects were also excluded if they were currently seeking medical care for LBP; were unable to participate in unit exercise owing to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand; had a history of fracture (stress or traumatic) in proximal femur, hip, or pelvis; were pregnant; or had transferred from another training group. Other possible exclusions included soldiers who were being accelerated into a company already randomized and recruited for participation in the Prevention of Low Back Pain in the Military trial or soldiers who were being reassigned to an occupational specialty other than a combat medic.

Refer to Figure 1 for a flow diagram describing the number of patients considered for this trial, eventually enrolled into the trial, and completed follow-up assessment, as per the Consolidated Standards of Reporting Trials guidelines (17). The institutional review boards at the Brooke Army Medical Center (San Antonio, TX) and the University of Florida (Gainesville, FL) granted approval for this project. All subjects provided written informed consent before their participation.

Randomization. Military training environments require living in close quarters with other members of the unit, making individual randomization an unfeasible option for this trial because of concerns related to disruption of normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was used for assigning companies to receive TEP or CSEP. This meant that for a given company, every subject who consented to the study received the same study condition. Cluster randomization is a viable methodological choice that has been effectively used in other large samples of primary prevention (20,21,24). The randomization schedule was prepared by computer and was determined before recruitment began. The randomization schedule was balanced to ensure equal allocation to each condition after 12 companies were recruited.

Exercise programs. Subjects in both groups performed the assigned exercise program in a group setting
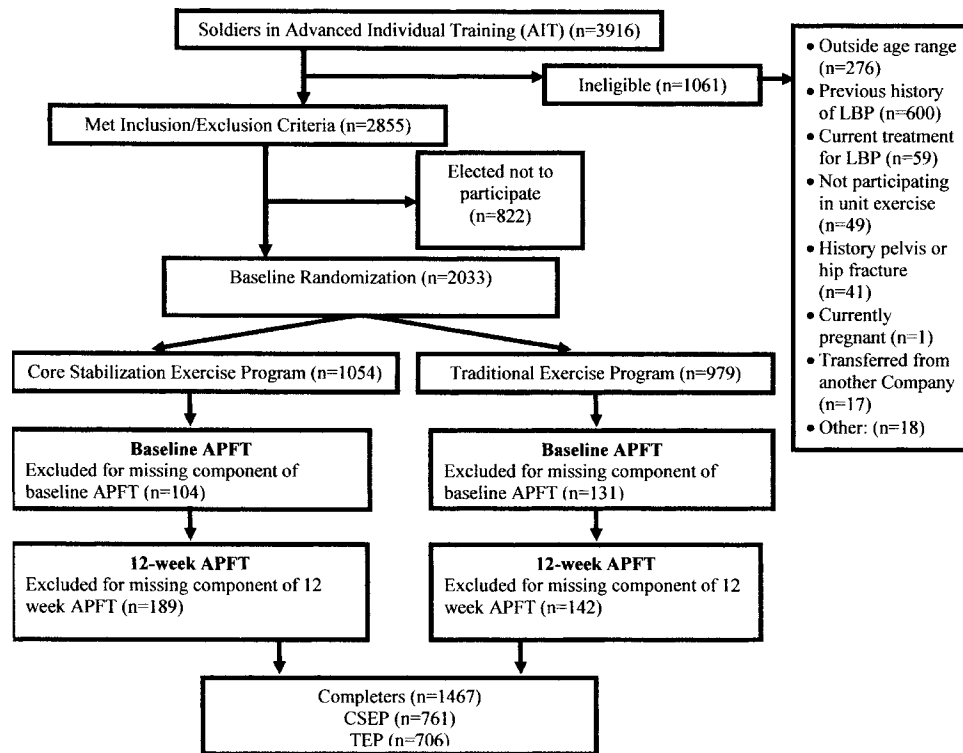
FIGURE 1—Flow diagram for patient recruitment and randomization. IET, initial entry training.

under the direct supervision of their drill instructors as part of daily unit physical training. The exercise regimen in both groups consisted of five to six exercises, each of which was performed for 1 min. Exercise programs were performed daily, for a total dosage time of approximately 5 min·d^{-1}, 4 d·wk^{-1} during a period of 12 wk. Performing the exercise programs under the supervision of a drill instructor and in a group setting helped to ensure compliance with the assigned program and dosage. Additional details regarding each exercise program is included in Table 1 and in the Appendix.

The subjects' drill instructors received comprehensive training in the study procedures by the staff before the study's initiation. Drill instructors were provided detailed training cards specific to each program. This information was also provided to the drill instructors on the study's Web site (http://polm.ufl.edu) for reference purposes. This training ensured that both the drill instructors and the subjects were proficient in their assigned exercise programs and enhanced the ability to accomplish the exercise programs in a standardized manner. Study personnel monitored physical training for an average of 2 d·wk^{-1} during the 12-wk training period to answer questions and to monitor compliance with the assigned exercise program.

Measurements. Study-related measures were collected by research personnel unaware of randomization assignment before training and 12 wk later when training was completed. All measures were scored in a masked manner by a computer algorithm. Subjects provided standard demographic information such as age, sex, past medical history, etc., and completed a variety of health outcome measures. It was not possible to blind subjects to group assignment because they actively participated in their randomly assigned training program. However, APFT fitness scores were collected by drill instructors according to standard testing procedures outlined later (2). The drill instructors were not formally involved with the study other than within the context of the usual training environment.

APFT procedures. Subjects' physical fitness was assessed at baseline and after their randomly assigned 12-wk training program according to established Army standards for conducting the APFT (2). The APFT consists of three events: 1) maximum sit-up performance in 2 min, 2) maximum push-up performance in 2 min, and 3) a timed 2-mile run. Scores for each event are based on age- and sex-stratified normative data and ranged from 0 to 100 points

TABLE 1. Comparison of the CSEP and the TEP.

Exercise	CSEP	TEP
Principle	Lower load, less repetitions	Higher load, more repetitions
Speed	Slower	Faster
Trunk movements	None to minimal	Full
Dosage	5 min·d^{-1}	5 min·d^{-1}
No. 1	Abdominal drawing-in maneuver crunch	Traditional sit-up
No. 2	Left and right horizontal side support	Sit-up with left trunk rotation
No. 3	Hip flexor squat ('woodchopper')	Sit-up with right trunk rotation
No. 4	Supine shoulder bridge	Abdominal crunch
No. 5	Quadruped alternate arm and leg	Traditional sit-up

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Variable	All Soldiers (*n* = 1467)	CSEP (*n* = 761)	TEP (*n* = 706)
Age (yr)	21.9 (4.3)	21.9 (4.4)	21.9 (4.1)
Sex (% male)	73.3	72.5	74.2
Body mass index (kg·m^{-2})	24.7 (4.0)	24.8 (4.3)	24.7 (3.7)
Currently smoke (%)	32.8	31.6	34.0
Previous routine exercise (%)	54.3	55.4	53.3

Values represent the mean (SD), except where noted otherwise. There were no differences between the groups in baseline demographic and the self-reported variables ($P > 0.05$).

for each event. A soldier must score at least 60 points in each of the three events to pass, thus a minimum passing score of 180 points. Failure to achieve at least 60 points in any single event, regardless of performance in the other two events, results in an overall failure.

The sit-up event of the APFT begins with the command "get set." Subjects lie on their backs with the knees bent at a 90° angle and the feet together or up to 12 inches apart. Another person holds the ankles. Other methods of bracing or holding the feet are not permitted. The heel is the only part of the foot that must stay in contact with the ground. The subjects' fingers must be interlocked behind the head, and the backs of the hands are required to touch the ground. The exercise commences when the subject begins raising the upper body to, or beyond, the vertical position. The vertical position is defined as the base of the subject's neck being above the base of the spine. After the subject has reached or surpassed the vertical position, the subject lowers his body until the bottom of his shoulder blades touch the ground. The subject's head, hands, arms, or elbows do not have to touch the ground. A repetition is not counted if the subject fails to reach the vertical position, fails to keep his fingers interlocked behind his head, arches or bows his back, raises his buttocks off the ground to raise his upper body, or lets his knees exceed a 90° angle. If the standard is not met, the repetition does not count and the scorer repeats the number of the subject's last correctly performed sit-up to let the subject know a violation occurred. The up position is the only authorized rest position. If the subject stops and rests in the down (starting) position, the event will be terminated. As long as the subject makes a continuous physical effort to sit-up, the event will not be terminated. The subject may not use his hands or any other means to pull or push himself to attain the up (resting) position or to hold himself in the rest position. If the subject does this, his performance will be terminated. The subject has 2 min to perform as many sit-ups as possible. The total number of sit-ups performed in 2 min is adjusted on the basis of sex and age according to established Army standards (2). Similar standards exist for the performance of the push-up and 2-mile run events.

Data analysis. Descriptive statistics, including measures of central tendency and dispersion for continuous variables, were calculated to summarize the data. Demographic and

TABLE 3. Overall age- and sex-adjusted sit-up scores (0–100 points) by group, quartile, and time.

	TEP (*n* = 761)			CSEP (*n* = 706)			Difference (CSEP − TEP)	
	Baseline (95% CI)	12 wk (95% CI)	Change from Baseline to 12 wk (95% CI)	Baseline (95% CI)	12 wk (95% CI)	Change from Baseline to 12 wk (95% CI)	Baseline (95% CI)	12 wk (95% CI)
All subjects (*n* = 1467)	77.6 (77.2 to 77.9)	82.0 (81.2 to 82.8)	4.5 (3.6 to 5.3)	77.1 (76.8 to 77.5)	79.8 (79.0 to 80.5)	2.6 (1.9 to 3.4)	−0.4 (−0.9 to 0.1)	−2.3 (−3.4 to −1.2)
25th percentile (*n* = 335) TEP: *n* = 119 CSEP: *n* = 216	58.4 (57.5 to 59.3)	70.8 (68.8 to 72.7)	12.4 (10.4 to 14.3)	58.3 (57.6 to 58.9)	69.4 (67.9 to 70.8)	11.1 (9.7 to 12.5)	−0.1 (−1.3 to 1.0)	−1.4 (−3.8 to 0.9)
50th percentile (*n* = 371) TEP: *n* = 170 CSEP: *n* = 201	72.5 (71.8 to 73.3)	77.4 (75.9 to 79.0)	4.9 (3.3 to 6.6)	72.4 (71.7 to 73.1)	75.1 (73.6 to 76.6)	2.7 (1.2 to 4.2)	−0.1 (−1.1 to 0.9)	−2.3 (−4.5 to −0.2)
75th percentile (*n* = 383) TEP: *n* = 199 CSEP: *n* = 184	82.4 (81.7 to 83.1)	85.5 (84.0 to 86.9)	3.1 (1.6 to 4.5)	82.3 (81.5 to 83.0)	82.3 (80.8 to 83.9)	0.1 (−1.5 to 1.6)	−0.1 (−1.1 to 0.9)	−3.1 (−5.2 to −1.0)
100th percentile (*n* = 378) TEP: *n* = 218 CSEP: *n* = 160	96.9 (96.2 to 97.6)	94.4 (93.0 to 95.8)	−2.5 (−3.9 to −1.1)	95.6 (94.8 to 96.4)	92.2 (90.6 to 93.9)	−3.4 (−5.1 to −1.7)	−1.3 (−2.3 to −0.3)	−2.1 (−4.3 to 0.0)

Table shows within- and between-group changes from baseline to 12 wk. There was no significant group × quartile × time interaction ($P = 0.543$). Both groups demonstrated significant improvements in their overall sit-up scores over time ($P < 0.001$ for both the TEP and CSEP groups). CI, confidence interval.

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TABLE 4. Overall APFT fitness scores (range = 0–300) at baseline and after 12 wk.

All Subjects (*n* = 1467)	Baseline (95% CI)	12 wk (95% CI)	Change from Baseline to 12 wk (95% CI)
TEP (*n* = 761)	234.2 (233.3 to 235.2)	243.7 (241.8 to 245.6)	9.5 (7.6 to 11.4)
CSEP (*n* = 706)	233.2 (232.3 to 234.1)	241.8 (240.0 to 243.6)	8.6 (6.8 to 10.4)
Difference (CSEP−TEP)	−1.1 (−2.4 to 0.2)	−2.0 (−4.6 to 0.7)	not applicable

There was no significant difference between groups in overall APFT fitness scores at 12 wk ($P = 0.142$). Both groups demonstrated significant improvements in their overall scores over time ($P < 0.001$).

baseline levels of variables were compared between the two randomly assigned groups using *t*-test for comparison of means and χ^2 tests for comparison of proportions.

Independent variables were group with two levels (TEP and CSEP), quartile with four levels (0%–25%, 26%–50%, 51%–75%, and 76%–100%), and time with two levels (baseline and 12 wk). Quartile was considered to determine whether there were differential effects on sit-up up performance at the extremes of the range of performance. Dependent measures were scores and pass rates for the sit-up event and overall APFT.

A 2 × 4 × 2 (group × quartile × time) repeated-measures ANOVA with pairwise comparisons using the Bonferroni inequality was performed to examine differences in the overall fitness and sit-up performance scores. Differences in pass rates were assessed with a χ^2. The α level was set to 0.05 *a priori*. Subjects with missing data were excluded because the purpose of this study was to determine the impact of performing CSEP in lieu of sit-ups on the basis of the condition that subjects actually completed the full training period.

The number needed to treat (NNT) is an epidemiological measure used in assessing the effectiveness of health-care interventions and conceptually represents the number of patients who need to be treated to prevent one additional bad outcome, thus lower NNT values imply fewer patients need to be treated to observe the benefit (14). We calculated the NNT statistic in this study to determine the relative impact of performing CSEP versus TEP to improve passing rates on the sit-up event of the APFT. In this instance, the "treatment" is the randomly assigned exercise training program (TEP or CSEP) and the "bad outcome" is a failure on the sit-up event of the APFT. All statistical analyses were performed using SPSS 12.0 (SPSS, Inc., Chicago, IL).

RESULTS

A total of 3916 subjects were screened for inclusion into the study. There were 1061 (27%) who were ineligible and therefore excluded from further consideration, leaving 2855 eligible subjects. The reasons for ineligibility included being outside the age range; having a history of LBP; currently seeking care for LBP; prior surgery for LBP; currently not performing physical training; having a history of fracture of the proximal femur, pelvis, or hip; being pregnant; or being transferred in from another company.

Among those eligible, 2033 subjects (71%) consented to participate (Fig. 1). There were 235 (11.6%) subjects for whom at least one event of the baseline APFT fitness score was missing because of a current injury that prevented them from completing the sit-up, the push-up, or the 2-mile run event, thus their data were excluded for the purposes of this proximal analysis. Of the remaining 1798 subjects, 331 (18.4%) did not have complete data for the 12-wk APFT fitness score, thus a total of 1467 subjects (81.6%; TEP: *n* = 706, TEP and CSEP: *n* = 761) were included in the completers-only analysis (Fig. 1).

The mean age of subjects was 21.9 ± 4.3 yr (73.3% male; Table 2). Descriptive statistics for each group categorized by quartile are included in Table 3. There was no significant group × time × quartile interaction for performance on either overall fitness ($P = 0.164$) or sit-up scores ($P = 0.543$) on the APFT (Table 3). Both groups demonstrated significant improvements in their sit-up scores ($P < 0.001$; Table 3) and overall fitness scores over time ($P < 0.001$; Table 4). Subjects in the top quartile for both groups demonstrated a small but significant decrease in sit-up performance from baseline to 12 wk ($P < 0.001$), indicating the potential for a ceiling effect to have occurred. Both groups performed

TABLE 5. Frequency (%) with which subjects performed sit-ups outside the unit physical training on the basis of the baseline sit-up score quartile.

	TEP	CSEP	*P*
25th percentile (*n* = 335)			
Did subjects perform sit-ups outside the unit physical training?	69.7	65.7	0.45
% yes (*n* = 230)			
If "Yes," how many days per week on average did subjects perform sit-ups outside the unit physical training?	9.4	9.0	
>5 d (*n* = 21)	36.5	39.3	0.91
3–5 d (*n* = 88)	54.1	51.7	
<3 d (*n* = 121)			
50th percentile (*n* = 371)			
% yes (*n* = 240)	64.7	60.2	0.37
>5 d (*n* = 27)	12.9	9.7	
3–5 d (*n* = 81)	33.6	33.9	0.72
<3 d (*n* = 132)	53.4	56.5	
75th percentile (*n* = 383)			
% yes (*n* = 270)	68.3	69.6	0.79
>5 d (*n* = 36)	10.6	16.3	
3–5 d (*n* = 101)	43.3	31.0	0.09
<3 d (*n* = 133)	46.1	52.7	
100th percentile (*n* = 378)			
% yes (*n* = 267)	74.3	65.0	0.05
>5 d (*n* = 45)	14.1	21.2	
3–5 d (*n* = 110)	43.6	37.5	0.29
<3 d (*n* = 112)	42.3	41.3	

If "yes," the number of days per week (%) on average that subjects performed sit-ups outside the unit physical training.

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TABLE 6. Passing rates (%) for the sit-up component (>60 points) and overall APFT fitness score (>180 points) score at baseline and after 12 wk.

All Subjects (n = 1467)	Baseline	12 wk	Change from Baseline to 12 wk	P
Sit-up				
TEP (n = 761)	93.8	97.7	3.9	
				0.004
CSEP (n = 706)	89.1	94.7	5.6	
Overall				
TEP (n = 761)	78.3	89.8	11.5	
	P = 0.02	P < 0.001		
CSEP (n = 706)	73.1	83.6	10.5	

Both groups demonstrated significant improvements in sit-up and overall pass rates over time ($P < 0.001$). There was also a small but significantly greater increase in sit-up passing rates with CSEP versus TEP.

sit-ups outside the unit physical training at equal rates overall (TEP = 69.5% and CSEP = 65%; $P = 0.067$) and equal frequencies on the basis of days per week (<3, 3–5, and >5 d; $P = 0.320$). Table 5 also displays the frequencies with which subjects in each group performed sit-ups outside the unit physical training on the basis of the baseline sit-up score quartile. Regardless of the baseline sit-up quartile, there were no significant differences in the percentage of subjects who performed sit-ups outside the unit physical training (Table 5).

There was also no significant group × time interaction for either the score of the overall APFT fitness ($P = 0.142$; Table 4) or the score on the sit-up component of the APFT ($P = 0.543$; Table 3) after 12 wk of training; however, CSEP resulted in a significant improvement in sit-up passing rates by 5.6% compared with 3.9% for the TEP group ($P = 0.004$; Table 6). The corresponding NNT for CSEP to improve passing rates on the sit-up event of the APFT was 56.

DISCUSSION

The results of this study suggest that performing core stabilization exercises in lieu of traditional sit-ups during unit physical training did not have a deleterious impact on either performance or passing rates for sit-up or overall fitness as assessed with the APFT. Both groups significantly improved their overall fitness and sit-up performance on the APFT at a similar rate between the baseline and the 12-wk follow-up, suggesting that the omission of sit-ups during unit physical training in favor of a CSEP does not lead to decrements in performance on the APFT. In fact, there was a small but significantly greater increase in sit-up passing rates with CSEP (5.6%) versus TEP (3.9%).

The baseline to 12-wk change data in Table 6 represent a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP group (3.9%). Therefore, to help interpret the meaningfulness of this finding, we calculated the NNT for CSEP to improve passing rates on the sit-up event of the APFT, which was 56. In other words, in a company of 400 soldiers, approximately 34 soldiers

will fail the sit-up event of the APFT. After 12 wk of TEP, 15 of those 34 soldiers would improve from a failing to a passing score on the sit-up event. Conversely, 22 of 34 subjects in the CSEP group would progress from a failing score to a passing score, indicating that performing CSEP resulted in a net seven additional subjects progressing from a failing to a passing score on the sit-up event of the APFT compared with TEP. It is possible that the significant improvement in passing rates observed in favor of the CSEP group (Table 6) may represent a type I error due to the large sample size, thus bringing into question the meaningfulness of this finding. Nevertheless, these data may be important to consider in future research and to inform policy decision making regarding the potentially protective role of CSEP on sit-up performance.

The results of this study differ in several ways from the findings of Baxter et al. (5). For example, our population consisted of enlisted soldiers in the military with an average baseline sit-up score of 77%. This is a more representative population of the Army as a whole compared with Baxter who included officer candidate cadets at US Military Academy at West Point, with an average baseline sit-up score of 95% (5). Furthermore, the composition of the exercise programs and dosing of the intervention was different. The training program in the Baxter study was limited to performing abdominal crunches for 6 wk (5), whereas the subjects in our study performed 12 wk of a CSEP composed of abdominal crunches among a more comprehensive trunk strengthening program. Despite these differences, both studies found no decrease in sit-up performance when traditional sit-ups were omitted from a physical training program for a maximum of 12 wk (5).

One of the potential confounding factors anticipated before the study was that subjects in the CSEP group might not be compliant with the instructions to avoid performing sit-ups outside the unit physical training because of perceived deleterious impact that not performing sit-ups might have on their APFT fitness scores. It was unrealistic to precisely control for sit-up exposure outside the unit physical training because graduation from training and opportunity for promotion are dependent on passing the fitness test; therefore, we assessed compliance with the assigned training program as part of the 12-wk follow-up by assessing the extent to which subjects in each group performed sit-ups outside the unit physical training. Subjects in both groups performed sit-ups outside the unit physical training at equal rates (TEP = 69.5% and CSEP = 65%; $P = 0.067$); therefore, only 35% of subjects in the CSEP group did not perform sit-ups outside the unit physical training. However, there was no difference between the groups in the frequency with which subjects performed sit-ups outside the unit physical training (<3, 3–5, and >5 d). It may be that the frequency of performing sit-ups outside the unit physical training may simply be an indicator of the normal amount of training that

routinely occurs outside the more formal unit physical training.

We further analyzed the frequency of performing sit-ups outside the unit physical training on the basis of the baseline sit-up quartile if subjects more at risk for suboptimal performance on the APFT (0–50th percentile) and who were assigned to the CSEP might be more inclined to perform sit-ups outside the unit physical training compared with subjects in the TEP group in the same quartile. However, there were no significant differences in the frequency of performing sit-ups outside the unit physical training between the groups regardless of quartile. Although there were trends for differences between the groups in the 100th percentile ($P = 0.05$; Table 5), the difference was in favor of the TEP; thus, this finding does not support the argument that performing sit-ups outside the unit physical training in the CSEP confounded the results.

It might also be expected that subjects in the CSEP group who performed additional sit-ups would demonstrate improved sit-up performance and passing rates on the APFT compared with subjects who did not, again confounding the study's interpretation. However, a sensitivity analysis revealed no difference in sit-up performance and overall passing rates on the APFT between subjects in the CSEP group who performed sit-ups outside the unit physical training and those who did not. This finding lends further evidence to suggest that the performance of additional sit-ups outside the unit physical training did not confound the results and reinforces the notion that soldiers, commanders, and health policy decision makers should not be concerned that performing CSEP in lieu of sit-ups will lead to decreased performance on the APFT. It should be noted that because both groups performed sit-ups outside the unit physical training at equal rates, the results of the study may be attributable to CSEP plus sit-up training outside the unit physical training compared with TEP plus sit-up training outside the unit physical training.

Another potential concern was that subjects in the CSEP group who were on the margin of failing the sit-up event on the APFT at baseline (0–50th percentile) might be more adversely impacted by CSEP than subjects with preexisting performance levels above the passing thresholds (51st to 100th percentile) because even small decrements or failure to improve sit-up performance among subjects in the lower quartiles could pose an increased risk of not passing the sit-up event. Conversely, it would take a large negative change in sit-up performance to impact passing rates among subjects in the top quartiles, even if CSEP was found to be associated with decreased sit-up performance. In other words, it is logical to presume that subjects in the top two quartiles would likely pass the sit-up event on the APFT regardless of group assignment. However, it turned out that there was no significant quartile effect overall, meaning that within each quartile, subjects improved their scores at a similar rate, regardless of whether they completed TEP or CSEP.

Subjects in the top quartile for both groups demonstrated a small but significant decrease in sit-up performance during the 12-wk period. Given preexisting high levels of fitness, the potential to demonstrate improvements was minimal, thus indicating the potential for a ceiling effect to have occurred. However, the magnitude of this decrease (3.4 and 2.5 points for the CSEP and TEP groups, respectively) had no material impact on passing rates because these subjects' fitness level was already in the top quartile. Therefore, the results of this study may not be generalizable to subjects with exceptionally high levels of physical fitness. Further research could be conducted on elite athletes or other populations of soldiers with high levels of physical fitness using an extended scoring scale that could detect higher levels of physical fitness and incorporated factors related to the influence of motivation on fitness test performance.

Despite evidence from the biomechanical literature supporting the benefits of abdominal crunch and core stabilization exercises and data from this trial suggesting that performing these exercises does not have a deleterious impact on overall fitness or maximal performance of sit-up as assessed on the basis of the APFT, little information is available suggesting whether the increased loads encountered with traditional sit-ups actually contribute to increased injury rates. If this is the case, these data would discredit the validity of including sit-ups as a component of the unit physical training or assessing sit-up performance in the APFT. We can confidently conclude that future research can examine whether CSEP offers protection against the development of musculoskeletal injuries such as LBP without having to be unduly concerned that doing so will lead to substantial increases in failure rates on the APFT. The results of follow-up studies will assist policy makers in constructing the physical fitness training programs and fitness assessment methodologies that offer the most protection against developing musculoskeletal injuries and maintain optimal physical fitness.

CONCLUSIONS

Performing core stabilization exercise does not increase the risk of suboptimal performance of sit-ups or overall fitness as assessed with the APFT. Therefore, CSEP can be incorporated into physical fitness programs without concern that doing so will have a deleterious impact on sit-up performance or overall fitness scores. In fact, of a typical company of 400 soldiers, CSEP could result in 7 additional soldiers progressing from failing to passing the sit-up event compared with TEP, demonstrating the potential for core stabilization exercises to improve performance of sit-ups in those with the lowest fitness scores. Although the magnitude of this benefit on the APFT may be considered small and future research is needed to determine the extent to which an improvement in passing rates on the sit-up event with CSEP would be realized, we can confidently conclude that performing CSEP in lieu of traditional sit-ups during

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unit physical training does not result in a decrement in the overall fitness or sit-up performance and passing rates on the APFT. In light of these data that CSEP can be studied without concern for increasing failure rates on the APFT, combined with a potentially important benefit of actually improving APFT fitness scores, future research from the primary study will determine whether CSEP is protective against the development of musculoskeletal injuries such as LBP. These data can also be used to inform health policy decision making because it relates to designing optimal health and fitness training and assessment programs for both military and civilian populations.

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APPENDIX

TEP

The sit-up

The sit-up was to be performed as the first and last exercise in the set of five exercises.

Starting position (Fig. A1): On the command, "Start position, move," the subject was supine in standard sit-up position, knees bent at 90°, with hands interlocked behind the head.

Exercise instructions (Fig. A2): On the command, "Exercise position, move," the subject was to bend and lift the upper body until shoulders and hips were parallel. Then the subject was to return to the starting position. The subject was to perform as many repetitions as possible in 1 min.

The sit-up with trunk rotation

Starting position (Fig. A1): On the command, "Start position, move," the subject was supine in standard sit-up position, knees bent at 90°, with hands interlocked behind the head.

FIGURE A1—Start and end position for the sit-up, the sit-up with trunk rotation, the abdominal crunch, and the abdominal drawing-in crunch maneuver.

Exercise instructions (Fig. A3): On the command, "Exercise position, move," the subject was to lift, bend, and rotate the upper body to the left until the right elbow touches the outside portion of the left knee. Then the subject was to return to the starting position. The subject was to perform as many repetitions as possible in 1 min to

FIGURE A2—Exercise position for the sit-up.

FIGURE A3—Exercise position for the sit-up with trunk rotation.

FIGURE A4—Exercise position for the abdominal crunch.

the left side and then repeat above to the right side for as many repetitions as possible in 1 min.

The abdominal crunch

Starting position (Fig. A1): On the command, "Start position, move," the subject was supine in standard sit-up position, knees bent at 90°, with hands interlocked behind the head.

Exercise instructions (Fig. A4): On the command, "Exercise position, move," the subject was to lift the upper body from the ground until the bottom borders of the shoulder blades cleared the ground and then quickly return to the start position. The subject was to perform as many repetitions as possible in 1 min.

CSEP

The abdominal drawing-in crunch maneuver

Starting position (Fig. A1): On the command, "Start position, move," the subject was supine in standard sit-up position, knees bent at 90°, with hands interlocked behind the head.

Exercise instructions (Fig. A5): On the command, "Exercise position, move," the subject was to draw abdominal muscles up and in toward the spine, then lift the upper body from the ground until the bottom borders of

FIGURE A5—Exercise position for the abdominal drawing-in crunch maneuver.

FIGURE A6—Start and end positions for the horizontal side support.

FIGURE A8—Start and end positions of the supine shoulder bridge.

the shoulder blades clear the ground. This position was to be held for 10 s. Six repetitions of this exercise were to be performed in 1 min.

The horizontal side support

Starting position (Fig. A6): On the command, "Start position, move," the subject was to lie on the right side with knees straight, left leg resting in front of the right leg and upper body supported with the right elbow, with the left hand supporting the right shoulder.

Exercise instructions (Fig. A7): On the command, "Exercise position, move," the subject was to draw in the abdominal muscles, and for a count of 5, lift the body from the ground with the body weight supported by the arms and feet. This position was to be held for 5 s. Then the body was to lower to the ground during a count of 5. The subject was to perform six repetitions of this exercise on the right side for 1 min and then repeat six repetitions of this exercise on the left side for 1 min.

The supine shoulder bridge

Starting position (Fig. A8): On the command, "Start position, move," the subject was supine in standard sit-up position, knees bent at 90°, with hands interlocked behind the head and instructed to pull in the abdominal muscles as in the abdominal drawing-in crunch maneuver.

Exercise instructions (Fig. A9): On the command, "Exercise position, move," for a count of 5 s, the subject

FIGURE A9—Exercise position for the supine shoulder bridge.

was to raise the hips and lower back off the ground until the body from the trunk to knees was in a straight line, with weight evenly distributed on the shoulders and feet. With the buttocks still raised, one leg was to be straightened out until it was in line with the trunk and thigh. This elevated position was to be held for 5 s in the elevated position and then lowered to the ground during a count of 5. With each repetition, the subject was to alternate each leg that was extended. The subject was to perform four repetitions of this exercise in 1 min.

FIGURE A7—Exercise position for the horizontal side support.

FIGURE A10—Start and end positions for the quadruped alternating arm and leg.

FIGURE A11—Exercise position for the quadruped alternating arm and leg.

The quadruped alternating arm and leg

Starting position (Fig. A10): On the command, "Start position, move," the subject was to assume the quadruped position on the hands and knees and instructed to pull in the abdominal muscles as in the abdominal drawing-in crunch maneuver.

FIGURE A13—Exercise position for counts 1 and 3 of the woodchopper.

Exercise instructions (Fig. A11): On the command, "Exercise position, move," for a count of 5 s, the subject alternately extended one leg and the opposite arm. This position was held for 5 s. Then both extremities were

FIGURE A12—Start and end positions for the woodchopper.

FIGURE A14—Exercise position for counts 2 and 4 of the woodchopper.

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lowered to the ground during a count of 5. This movement was repeated with the opposite arm and leg. The subject was to perform four repetitions in 1 min.

The woodchopper

Starting position (Fig. A12): On the command, "Start position, move," the subject was to assume a straddle stance with the arms overhead, hands joined, and fingers interlaced. They were further instructed to make sure to have the hips set, abdominals tightened, and arms extended as fully overhead as possible.

Exercise instructions: Count 1 (Fig. A13)—On the command, "Exercise position, move," the subject was to begin squatting with the heels flat while lowering the arms between the knees. The shoulders, knees, and balls of the feet should be aligned and the trunk should remain straight and tilted forward with the heels remaining on the ground. Count 2 (Fig. A14)—The subject was to move through the starting position to rise onto the balls of the feet, making sure not to let the trunk arch backward. Count 3 (Fig. A13)—The subject was to begin squatting with the heels flat while lowering the arms between the knees. The shoulders, knees, and balls of the feet should be aligned. The trunk should remain straight and tilted forward with the heels remaining on the ground. Count 4 (Fig. A14)—The subject was to move through the starting position to rise onto the balls of the feet, making sure not to let the trunk arch backward. Completion of counts 1–4 of the exercise sequence at a moderate pace constituted completion of one repetition of this exercise. This exercise was to be performed rhythmically for 1 min. After the last repetition, the subject was to halt at the starting position.

ORIGINAL ARTICLE

Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting

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Abstract The general population has a pessimistic view of low back pain (LBP), and evidence-based information has been used to positively influence LBP beliefs in previously reported mass media studies. However, there is a lack of randomized trials investigating whether LBP beliefs can be modified in primary prevention settings. This cluster randomized clinical trial investigated the effect of an evidence-based psychosocial educational program (PSEP) on LBP beliefs for soldiers completing military training. A military setting was selected for this clinical trial, because LBP is a common cause of soldier disability. Companies of soldiers ($n = 3,792$) were recruited, and cluster randomized to receive a PSEP or no education (control group, CG). The PSEP consisted of an interactive seminar, and soldiers were issued the *Back Book* for reference material. The primary outcome measure was the back beliefs questionnaire (BBQ), which assesses inevitable consequences of and ability to cope with LBP. The BBQ was administered before randomization and 12 weeks later. A linear mixed model was fitted for the BBQ at the 12-week follow-up, and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of greater than two points. Sensitivity analyses were performed to account for drop out. BBQ scores (potential range: 9–45) improved significantly from baseline of 25.6 ± 5.7 (mean $\pm$ SD) to 26.9 ± 6.2 for those receiving the PSEP, while there was a significant decline from 26.1 ± 5.7 to 25.6 ± 6.0 for those in the CG. The adjusted mean BBQ score at follow-up for those receiving the PSEP was 1.49 points higher than those in the CG ($P < 0.0001$). The adjusted odds ratio of BBQ improvement of greater than two points for those receiving the PSEP was 1.51 (95% CI $= 1.22$–1.86) times that of those in the CG. BBQ improvement was also mildly associated with race and college education. Sensitivity analyses suggested minimal influence of drop out. In conclusion, soldiers that received the PSEP had an improvement in their beliefs related to the inevitable consequences of and ability to cope with LBP. This is the first randomized trial to show positive influence on LBP beliefs in a primary prevention setting, and these findings have potentially important public health implications for prevention of LBP.

Keywords Primary prevention · Patient education · Biopsychosocial · Public health

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Introduction

Low back pain (LBP) is a common chronic musculoskeletal disorder [19, 32] that causes significant disability [2, 31, 33, 40]. Specifically, LBP has been associated with the inability to obtain or maintain employment [31] and lost productivity while still employed [33]. Cost-effective interventions for LBP are a research priority given its adverse impact on society [10]. Providing evidence-based education is one example of a cost-effective intervention for LBP.

Educational approaches based solely on anatomical explanations of LBP are known to be inadequate given the contemporary understanding of a biopsychosocial conceptualization of LBP [17, 26, 37]. Currently, it is recommended that patient education for LBP de-emphasizes the anatomical cause of the pain, encourages the patient to focus on resuming activity, teaches the patient to view LBP as a common condition, and reinforces the importance of maintaining positive attitude and coping styles [36, 38].

This change in education approach has had a positive influence on management of existing LBP. For example, advice to stay active and resume normal activities was more effective than usual medical care for LBP in separate randomized trials [14, 15, 18]. Psychosocial education that encourages positive coping was associated with decreased work absence in a quasi-experimental study [34]. The *Back Book* [27] is a pamphlet that delivers standard, evidenced-based information consistent with a biopsychosocial model, and has been used in randomized clinical trials demonstrating reduced disability and fear-avoidance beliefs in general practice [8] and physical therapy settings [12]. A quasi-experimental study also indicated that general practice patients given the *Back Book* reported higher patient satisfaction ratings and lower rates of persistent LBP [10].

Although these secondary prevention findings are important, less evidence is available to inform decision-making regarding whether psychosocial education can be effective in primary prevention of LBP. In an effective primary prevention model, evidence-based information would alter unwarranted beliefs about the consequences and management of LBP, as well as reduce the fear and threat of experiencing LBP. Understanding whether favorably altering beliefs about LBP before LBP develops has become a critical research priority given the huge cost burden of LBP on society [3, 20] and the pessimistic views held by the general population about the consequences of LBP [13].

Several population-based studies have investigated the primary prevention effects of psychosocial information on LBP delivered by media campaigns [6, 7, 39, 43]. Collectively these studies demonstrated a positive shift in LBP beliefs [6, 7, 39, 43], with persistent effects noted 3 years later by Buchbinder et al. [5]. Although these results are encouraging, these population-based studies utilized quasi experimental [7, 43] and "pragmatic observational" [39] methodologies; no randomized trials have been reported to date. Therefore, the purpose of this paper is to report the effect of an evidence-based PSEP on LBP beliefs for soldiers completing military training and participating in an ongoing cluster randomized clinical trial. This particular setting was selected for this study, because disability from LBP is commonly experienced in the military [16, 29] and favorable shifts in LBP beliefs before LBP is experienced could potentially alter this trend.

Materials and methods

Overview

The institutional review boards at the Brooke Army Medical Center (Fort Sam Houston, TX, USA) and the University of Florida (Gainesville, FL, USA) granted approval for this project. Consecutive soldiers entering the combat medic advanced individual training (AIT) at Fort Sam Houston, TX were considered for participation in this study. This study reported a planned analysis of a proximal outcome of the prevention of low back pain in the military (POLM) clinical trial (NCT00373009) [11] which has been registered at http://clinicaltrials.gov.

The goals of this study were to twofold. First, we wanted to determine the efficacy of an implemented PSEP for improving LBP beliefs. Second, we wanted to investigate the potential of responder subgroups to the PSEP. Our a priori hypothesis was that soldiers receiving the education program would have an improvement in LBP beliefs, in comparison to those that not receiving the education program. We also investigated whether demographic or psychological factors were predictive of improvement in LBP beliefs to identify responder subgroups.

Subjects

Research staff at Fort Sam Houston, Texas introduced the study to individual companies of soldiers. Soldiers were screened for eligibility, and informed consent was obtained, as appropriate. For 12 consecutive months soldiers were screened for eligibility according to the following inclusion/exclusion criteria.

Inclusion criteria

- age 18 (or emancipated minor that is 17-year-old) to 35-year-old,

- participating in combat medic military occupational specialty (MOS) training,
- English speaking and reading.

Exclusion criteria

- prior history of LBP (operationally defined as LBP that limited work or physical activity, lasted longer than 48 h, and caused the subject to seek healthcare) or previous medical history for any surgery for LBP,
- currently seeking medical care for LBP,
- history of degenerative joint disease, arthritis, spine trauma or vertebral fractures, and/or spondylolisthesis,
- currently unable to participate in physical fitness training due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand injury,
- history of fracture (stress or traumatic) in proximal femur and/or pelvis,
- currently pregnant,
- previous failure of AIT.

Randomization

Military training environments requires living in close quarters with other members of the unit making individual randomization an unfeasible option for this trial due to concerns related to disruption of normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was utilized for assigning companies to receive or not receive the PSEP. This meant that for a given company, every soldier who consented to the study received the same study condition. Cluster randomization is viable methodological choice that has been effectively used in other large samples of primary prevention [23, 24, 42]. The randomization schedule was prepared by computer and was determined before recruitment began. The randomization schedule was balanced to ensure equal allocation to each condition after 18 companies were recruited.

Intervention

Companies of soldiers were randomized to receive or not receive the PSEP. It was not possible to mask soldiers in this study, because of the nature of the educational program. The interventions are described below.

Psychosocial educational program (PSEP)

The PSEP involved an educational session within the first 14 days of entering AIT. The session consisted of an interactive seminar designed by the POLM investigative team and was implemented by study personnel. The overall goal of the 45-min session was to emphasize current scientific evidence on LBP. The seminar covered topics related to the favorable natural history of LBP, lack of definitive anatomical causes of LBP, the importance of returning to normal activity, and decreasing fear-avoidance beliefs and pain catastrophizing when experiencing LBP. After the seminar, soldiers were involved in a question and answer session and issued *The Back Book* [27]. *The Back Book* was used as the educational supplement, because of our prior experience with it in a physical therapy clinical trial [12] and its prior association with positive shifts in patient LBP beliefs [8, 10].

Control group (CG)

The CG received no formal instruction on LBP. An anatomy-based education program was not appropriate for a comparison, because prior studies have demonstrated no favorable change in LBP beliefs [8, 12, 34]. Furthermore, use of a CG (as opposed to an alternate form of education) is consistent with the methodology from the previously reported population-based studies [6, 7, 39, 43].

Measurement

Study-related measures were collected by research personnel unaware of randomization assignment before AIT and 12 weeks later, when AIT was completed. All measures were scored in a masked manner by computer algorithm.

Primary outcome measure

The back beliefs questionnaire (BBQ) was the primary outcome variable for this study. The BBQ is a previously validated self-report questionnaire used to quantify beliefs about the likely consequences of having LBP [35]. The BBQ has 14 items with response options ranging from 1 (agree) to 5 (disagree), and only the nine inevitability items are included for scoring (potential range: 9–45). Higher BBQ scores are indicative of better LBP beliefs and indicate the potential of a better ability to cope with LBP [6, 7]. In addition to having sound psychometric properties, the BBQ has been used as an outcome measure in other studies investigating educational and mass media interventions [5–7, 34]. Use in this trial is appropriate for our hypotheses and will also allow for cross-study comparisons.

Other measures

Commonly implemented and previously validated self-report questionnaires were used to compare baseline

attributes for the intervention groups and to determine baseline influence on LBP belief outcomes. The medical outcomes survey 12-item short-form health survey (SF-12) was used as a self-report of health status for physical and mental function. The physical and mental component summary scales (PCS and MCS) were reported individually in this study because they are valid estimates of physical and mental health [41]. The state-trait anxiety questionnaire (STAI) [30] and Beck depression inventory (BDI) [9, 28, 44] were used to measure negative affect from generalized anxiety and generalized depression, respectively. Nine items from the fear of pain questionnaire (FPQ-III) were used to measure fear about specific situations that normally produce pain [1, 21, 25].

Sample size estimation

In a previous study from Buchbinder et al. [5.], it was estimated that a sample size of 550 provided 80% power to detect a shift in BBQ of 0.5 (at 0.05 significance). Our primary sample size estimation was based on determining the effect of education and exercise programs on the occurrence and severity of LBP episodes [11]. Such a sample size (16 companies, approximately 3,200 soldiers) provided adequate statistical power for the planned proximal outcome analysis of LBP beliefs, as well as the consideration of responder subgroups from various demographic and psychological factors.

Data analysis

Demographic and baseline levels of variables were compared between the two randomly assigned groups using t test for comparison of means and chi-square tests for comparison of proportions. It was determined a priori that variables significantly different between the two groups would be considered in the final analyses, in addition to previously specified covariates of sex, age, and race.

First, we analyzed the 12-week follow-up completers only, as a liberal estimate of treatment effect. A linear mixed model was fitted for the BBQ at the 12-week follow-up in continuous scale, and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of more than two points. Two points was selected as a criterion of meaningful change in the BBQ, because it corresponded with previously reported thresholds in the literature such as 2-year population changes in BBQ scores that were associated with improvements in worker's compensation claims [7]. There was no sample-specific cut-off scores available for this part of the analysis, as the BBQ has not been previously studied in military samples.

A sensitivity analysis regarding missing data was conducted with the following 3-step process: (1) the dropout rates were compared across the education programs to assess systematic differences; (2) demographic and baseline levels of variables were examined for their relationship to dropout. Those variables related to dropout status were used to impute missing values for use in the intention to treat analysis of all soldiers; (3) comparison of the completers versus imputation analyses would provide an additional estimate of the effect of dropouts on hypothesis tests. All statistical analyses were performed using the SAS software, version 9 (SAS Institute Inc, 1996).

Results

Refer to Fig. 1 for a flow chart describing the number of patients considered for this trial, eventually enrolled into the trial, and completed follow-up assessment, as per CONSORT guidelines [22]. Descriptive statistics for the sample ($n = 3,792$) are summarized in Table 1. There were small post randomization differences noted for the PSEP and CG, such that soldiers assigned to PSEP had worse BBQ scores, were older, more likely to have college level or more education, and more likely to have enlisted in the army for 1–3 years ($P < 0.01$). These variables were included as covariates in the subsequent analyses.

The BBQ score improved significantly ($P < 0.0001$) from baseline of 25.6 ± 5.7 (mean $\pm$ SD) to 26.9 ± 6.2 at the 12-week follow-up for those receiving the PSEP, while there was a significant decline ($P < 0.0001$) from 26.1 ± 5.7 to 25.6 ± 6.0 for those in the CG (Fig. 2). The effect sizes of BBQ change were 0.18 and -0.10, for the PSEP and CG groups, respectively. These differences favoring the PSEP for BBQ scores were statistically significant at the 12-week follow-up ($P < 0.0001$). Table 2 presents the results of linear mixed modeling of the BBQ at the 12-week follow-up and the results of generalized linear mixed models for the dichotomous outcomes of BBQ improvement (greater than two points). The adjusted mean improvement for those receiving the PSEP was 1.49 points higher than those in the 4CG ($P < 0.0001$). The adjusted odds ratio of BBQ improvement for those receiving the PSEP was 1.51 (95% CI = 1.22–1.86) compared to those in the CG.

BBQ score at intake, older age, female, race other than white, college education or higher are significantly associated with higher BBQ score at the follow-up. When psychological factors were investigated, only fear of pain and depression were statistically associated with BBQ follow-up score. These psychological associations were small in magnitude, as every unit increase in FPQ and BDI was associated with a 0.04 and 0.10 point lower follow-up BBQ score, respectively. The analyses investigating subgroup responder characteristics indicated potential
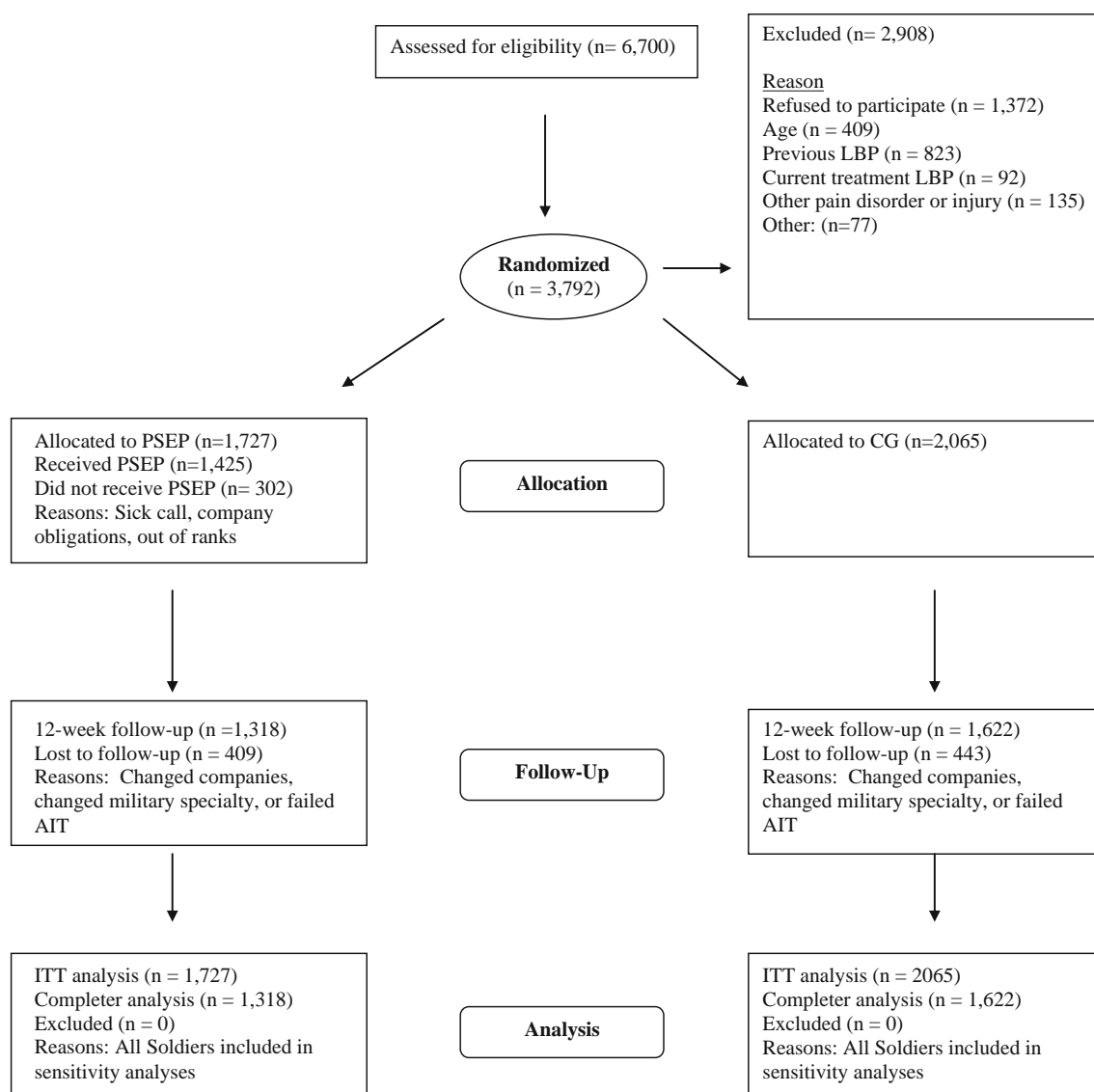
Fig. 1 Summary of recruitment, enrollment, follow-up, and analysis for psychosocial education trial. *LBP* low back pain, *PSEP* psychosocial education program, *CG* control group, *AIT* advanced individual training, *ITT* intention to treat analysis

demographic influences on BBQ scores (Table 2). BBQ improvement for soldiers of race other than white had an odds ratio of 0.82 (95% CI: 0.69–0.98). College education or higher was also related to BBQ improvement, with an odds ratio of 1.23 (95% CI: 1.05–1.44). In contrast, none of the psychological variables were associated with BBQ improvement of greater than two.

There were no major changes in results when the sensitivity analyses were performed, suggesting minimal influence of study drop out. The CG had a higher drop out rate than the PSEP group (25.7 vs. 19.8%). The drop outs from the two groups had the same intake characteristics, except that proportion of soldiers of race other than white in the CG was higher than that of the PSEP group. There were significant differences ($P < 0.05$) from the soldiers,

who completed the follow-up ($n = 2,940$) at 12 weeks compared to those soldiers that dropped out ($n = 852$) in baseline BBQ, PCS, MCS, BDI, STAI, race, education level, and time enlisted in army. These variables were used to predict the BBQ at follow-up for those dropped out using a linear mixed model fitted based on complete data. Sensitivity analyses were then performed by running two separate models. The first model was an intention to treat analysis with all soldiers ($n = 3,792$) using the imputed outcome for those not completing follow-up. The second model was an analysis of the imputed outcome for only those soldiers ($n = 852$) not completing follow-up. In the intention to treat analysis, the adjusted mean BBQ scores at follow-up for those receiving the PSEP was 1.44 points higher than those in the CG ($P < 0.0001$), with an odds

Table 1 Sociodemographic and psychological characteristics of the military sample

Factors	Intake (n = 3,792)			Missed 12-week follow-up (n = 852)		
	Total	CG (n = 2,065)	PSEP (n = 1,727)	Total	CG (n = 443)	PSEP (n = 409)
BBQ total [mean (SD)]	25.9 (5.7)	26.1 (5.7)	25.6 (5.7)*	25.4 (5.6)	25.7 (5.5)	25.2 (5.7)
PCS total [mean (SD)]	53.5 (5.1)	53.5 (5.2)	53.4 (5.1)	52.8 (5.6)	52.9 (5.4)	52.6 (5.8)
MCS total [mean (SD)]	49.1 (8.6)	49.2 (8.6)	49.0 (8.7)	47.7 (9.8)	48.3 (9.5)	47.0 (10.1)
FPQ total [mean (SD)]	18.1 (5.8)	17.9 (5.9)	18.3 (5.7)	18.1 (6.1)	17.7 (6.3)	18.5 (5.9)
BDI total [mean (SD)]	6.4 (6.6)	6.4 (6.7)	6.3 (6.5)	7.9 (8.0)	7.8 (8.0)	7.9 (8.0)
STAI total [mean (SD)]	36.0 (9.2)	35.9 (9.3)	36.0 (9.0)	37.7 (9.8)	37.6 (10.0)	37.8 (9.7)
Age [mean (SD)]	22.0 (4.4)	21.6 (4.2)	22.4 (4.6)*	21.9 (4.4)	21.6 (4.1)	22.2 (4.7)
Race [n (%)]						
Other	1,049 (27.7)	581 (28.1)	468 (27.1)	288 (33.8)	173 (39.1)	115 (28.1)*
White or Caucasian	2,743 (72.3)	1,484 (71.9)	1,259 (72.9)	564 (66.2)	270 (61.0)	294 (71.9)
Gender [n (%)]						
Female	1,103 (29.1)	625 (30.3)	478 (27.7)	252 (29.6)	144 (32.5)	108 (26.4)
Male	2,689 (70.9)	1,440 (69.7)	1,249 (72.3)	600 (70.4)	299 (67.5)	301 (73.6)
Education [n (%)]						
College or more	2,028 (53.5)	1,073 (52.0)	955 (55.3)	391 (45.9)	195 (44.0)	196 (47.9)
High school or less	1,764 (46.5)	992 (48.0)	772 (44.7)	461 (54.1)	248(56.0)	213 (52.1)
Income [n (%)]						
$35,000 or more	665 (17.6)	322 (15.6)	343 (19.9)*	143 (16.8)	63 (14.3)	80 (19.7)
Less than $35,000	3,118 (82.4)	1,738 (84.4)	1,380 (80.1)	706 (83.2)	379 (85.8)	327 (80.3)
Time in army [n (%)]						
1–3 years	322 (8.5)	153 (7.4)	169 (9.8)*	54 (6.3)	25 (5.6)	29 (7.1)
<1 year	3,199 (84.4)	1,794 (87.0)	1,405 (81.4)	733 (86.0)	386 (87.1)	347 (84.8)
>3 years	269 (7.1)	116 (5.6)	153 (8.9)	65 (7.6)	32 (7.2)	33 (8.1)

BBQ back beliefs questionnaire, *PSEP* psychosocial education program, *FPQ-III* fear of pain questionnaire, *BDI* Beck depression inventory, *STAI* state trait anxiety index, *PCS* physical component summary, *MCS* mental component summary

* $P < 0.01$ in t tests for comparison of means and chi-square tests for comparison of proportions between the two randomly assigned groups
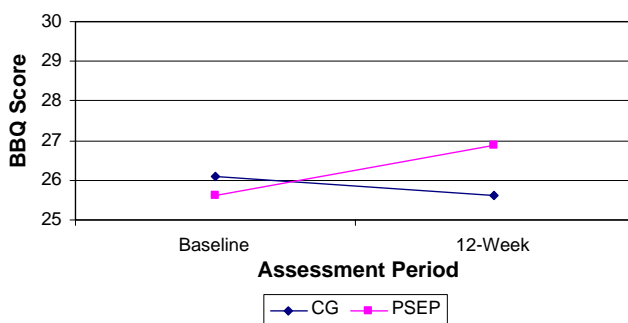
Fig. 2 Psychosocial education results in improvement in low back pain beliefs. *BBQ* back beliefs questionnaire, *CG* control group, *PSEP* psychosocial education program. Statistically significant differences were present at the 12-week assessment ($P < 0.0001$)

ratio for BBQ improvement of 1.75 (95% CI: 1.44–2.13). In the imputation outcome analysis the adjusted mean BBQ scores for those receiving the PSEP was 1.31 points higher than those in the CG ($P < 0.0001$), with an odds ratio for BBQ improvement of 2.10 (95% CI: 1.52–2.92).

Discussion

The general population has a pessimistic view on the consequences of LBP, and it has been hypothesized that such beliefs contribute to the development of disability from LBP [13]. Information that positively alters beliefs about LBP to better reflect current evidence has potential treatment implications in a variety of settings [7, 8, 10, 12, 39, 43]. Consecutive companies of soldiers were recruited for the current study, excluding those with a previous history of LBP or with a current musculoskeletal pain condition. Our findings suggested that for this cohort, the PSEP resulted in a small improvement in LBP beliefs and potential ability to cope with LBP. Our study included a CG that suggests the natural history of LBP beliefs is to slightly worsen in this particular environment. Although only a small effect size was associated with BBQ improvement, the current study adds to the existing literature as it is the first randomized trial to demonstrate positive influence on LBP beliefs in a primary prevention setting.

Table 2 Summary of analyses results for low back pain beliefs

Effects	BBQ total at follow-up (continuous)			BBQ improvement (categorical)			
	Estimate	SE	P value	Odds ratios	95% CI		P value
Intercept	15.66	2.35	<0.0001				
BBQ total at intake	**0.41**	**0.02**	**<0.0001**				
PSEP	**1.49**	**0.22**	**<0.0001**	**1.51**	**1.22**	**1.86**	**0.0001**
Age	**0.06**	**0.02**	**0.0090**	1.01	0.99	1.03	0.1939
Gender: female	**0.84**	**0.24**	**0.0004**	0.90	0.76	1.07	0.2217
Race: others	−0.23	0.24	0.3271	**0.82**	**0.68**	**0.96**	**0.0128**
Education: college or more	**0.45**	**0.22**	**0.0401**	**1.23**	**1.05**	**1.44**	**0.0106**
Income: $35,000 or more	−0.13	0.28	0.6374	1.00	0.82	1.22	0.9722
Time in army: 1–3 years	0.51	0.54	0.3432	1.11	0.76	1.62	0.5814
Time in army: <1 year	−0.03	0.42	0.9516	0.95	0.71	1.27	0.7344
FPQ-III total at intake	**−0.04**	**0.02**	**0.0205**	1.00	0.99	1.02	0.5859
BDI total at intake	**−0.10**	**0.02**	**<0.0001**	0.99	0.97	1.01	0.1905
STAI total at intake	−0.01	0.02	0.7679	1.01	0.99	1.02	0.3146
PCS total at intake	0.00	0.02	0.8621	1.00	0.98	1.02	0.9922
MCS total at intake	−0.02	0.02	0.1889	1.00	0.99	1.01	0.9270

Continuous outcome was calculated by raw change score and categorical outcome was defined as yes/no depending whether BBQ score increased more than two points from time of intake to follow-up. Statistically significant predictors are indicated in bold font ($P < 0.05$)

BBQ back beliefs questionnaire, *PSEP* psychosocial education program, *FPQ-III* fear of pain questionnaire, *BDI* Beck depression inventory, *STAI* state trait anxiety index, *PCS* physical component summary, *MCS* mental component summary

These results are consistent with earlier findings on improving LBP beliefs from population-based studies that used quasi-experimental or observational designs in Australia [5–7], Scotland [39], and Norway [43]. Although the evidence-based educational messages regarding LBP were likely similar across all studies, the current study incorporated one time, group instruction as compared to information delivered by radio, television, or print advertisements. The current study had the shortest follow-up time (12 weeks), while previously reported studies had follow-up times up to 3 years. Despite these methodological differences, there appears to be converging evidence that LBP beliefs can be effectively altered with evidence-based information delivered by a variety of mediums.

The relevance of the observed improvement in LBP beliefs is an important consideration when interpreting the results of this trial; yet definitive clinically important thresholds for BBQ change have not been reported. We utilized a BBQ change criterion based on the initial Buchbinder et al. [6, 7] studies that reported that a 2-year mean BBQ change of 1.9 was associated with decreased rates of compensation claims [7]. In contrast, we reported a smaller mean improvement of 1.5 in BBQ scores at 12 weeks. This smaller magnitude of change and earlier outcome assessment indicate a smaller potential for affecting future reports of disability and pain [7]. One reason for a smaller effect size in the current trial could be that the previously reported study [7] utilized quasi-

experimental methodology, which has the potential to overestimate treatment effects [4]. Other equally plausible reasons for the smaller effect size observed in our study include the previously mentioned differences in study populations, and the mass media campaign by Buchbinder et al. [7] was more effective than a single session PSEP.

Another part of our analysis was to determine if demographic predictors of success existed, suggesting the potential for responder subgroups to exist. These analyses indicated that soldiers of race other than white were less likely to report a BBQ improvement (OR = 0.82), while those with college education or higher were more likely to report a BBQ improvement (OR = 1.23). These results suggest the potential of cultural or socioeconomic influences on the alteration of LBP beliefs. We are hesitant to speculate further on these influences, because these findings are preliminary and their theoretical implications are beyond the scope of the current manuscript. The only other available report is from Buchbinder et al. [5], who have reported similar levels of BBQ improvement across most demographic factors, with only upper white-collar workers having larger BBQ changes. Additional research is necessary to replicate these findings and determine if race or education status can be used to identify LBP belief responder subgroups.

Previous studies have not considered psychological factors, and our study suggests that fear of pain and depression was predictive of BBQ follow-up scores.

However, these associations were quite small, suggesting these baseline psychological factors have only a minimal influence on BBQ outcome. Contrary to our expectations, baseline psychological factors were not associated with BBQ change greater than two. Psychological distress has been consistently associated with the development of chronic LBP [17, 26], and we expected those with higher pre-morbid levels of anxiety, depression, and fear of pain to have a stronger association with BBQ improvement. However, this was not the case in the current trial, as only weak statistical associations with follow up scores existed. A possible explanation for these unexpected findings could be that psychological distress levels were very low in this particular setting (Table 1), and these low levels had minimal potential to influence LBP beliefs. Another explanation is that the psychological factors of interest have a strong influence on LBP beliefs but only when individuals are actively experiencing LBP. Overall the responder analyses suggest that for this setting the PSEP intervention should not be considered for targeted application to psychological subgroups. However, future studies in different primary prevention cohorts with wider ranges of psychological distress are necessary to further investigate this issue.

The primary limitation of this study is that we did not investigate the LBP beliefs after 12 weeks or the effect of the PSEP on subsequent reports of pain, disability, and health care utilization. Pain, disability, and health care utilization are important outcomes to consider and these will be considered as 2-year endpoints in the ongoing POLM trial [11]. PSEP effect on LBP beliefs was an important factor to establish before determining pain, disability, and health care utilization as distal outcomes, because previous studies on the topic had not used randomized trial methodology. Another limitation is that this study was performed in a military setting, while the other studies in this area were performed with general populations. Although disability from LBP is a major problem across both of these settings, caution should be used when attempting to generalize our results to the general population. The use of a CG allowed us to determine the 12-week natural history of LBP beliefs, but it is also another limitation of this study. The effects of this particular PSEP are in reference to the CG, not a comparison education session.

Conclusion

This is the first randomized trial to show positive influence on LBP beliefs following a PSEP implemented in a primary prevention setting. In contrast, LBP beliefs slightly deteriorated for those in the CG. Though only small effect sizes were observed, these findings have potentially important public health implications for prevention of LBP. Future study will involve continuing the POLM trial to collect reports of LBP occurrence, severity, and health care utilization over the next 2 years [11]. These endpoints will allow us to make broader conclusions about the effectiveness of the PSEP for clinical presentation of LBP. Future study will also involve providing the same PSEP to health care providers and determine whether it positively influences professional advice given for treatment of LBP. Last, the same PSEP could be investigated to determine if it has public health implications for environments outside of the military, for example its effects on LBP beliefs in schools, universities, occupational, or clinical settings.

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Mental Health Symptoms in Combat Medic Training: A Longitudinal Examination

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ABSTRACT   Mental health symptoms in military populations are rising and constitute a significant health concern. This study examined the prevalence of depression, anxiety, and suicidal ideation in soldiers ($N = 3,792$) undergoing combat medic training. At the start of training, 10.4%, 15.5%, and 4.1% of soldiers had clinically significant depression, anxiety, or suicidal ideation, respectfully. These percentages increased to 12.2%, 20.3%, and 5.7% at completion of training, respectfully. Worsening of depression, anxiety, and suicidal ideation occurred for 7.7%, 11.4%, and 4% of soldiers. Higher percentages of symptoms were associated with females, lower education, and lower income. Active duty personnel were more likely to worsen following training with respect to suicidal ideation (OR = 1.9, 95% CI = 1.2–2.9) compared to reservists. The identification of these significant predictors of mental health status may serve to identify individuals at risk. Additional work to examine the relative contribution of anticipatory (impending deployment) factors vs. training-related factors is warranted.

INTRODUCTION

Recent reports[1–3] have highlighted the concern over depression and suicide in military populations. In addition to the scientific literature, reports about mental health issues in the military have become frequent in the popular press.[4] Moderate or greater depression has been reported in 15.9% of entry level military personnel.[1] Both male (15%) and female (22%) personnel reported depressive symptomatology. A recent study by the Rand corporation[4] indicated that approximately 18.5% of U.S. service members returning from current conflicts in Iraq and Afghanistan suffered from depression or post-traumatic stress disorder. Thus, both scientific literature and popular media accounts suggest a large number of U.S. military personnel involved in current conflicts report significant mental health problems.

Related to the above-mentioned depression rates are reports that military personnel have significant rates of suicidal ideation.[2,5,6] Army reports[6] indicate a significant increase in suicides since recording began in 2002. There were 350 reported suicides in 2002, and 2,100 reported in 2007. This same report indicated that the majority of suicides occurred stateside and included both formerly deployed and those who had not been deployed.

Predictors of mental health (primarily depression) and suicide in military populations have not received adequate research attention.[2] Although similar to predictors in the civilian population,[7] Allen and colleagues[2] noted that the branches of the military need additional military-specific information about factors related to suicide. They suggested that viable candidate factors included deployment status, combat stress, alcoholism, and sex/gender.

The purpose of this study was to examine mental health symptoms (depression, suicidal ideation, and anxiety) in a sample of soldiers enrolled in combat medic training. The data were collected as part of a longitudinal study examining back pain in the military and offered a relatively unique opportunity to examine the aforementioned mental health symptoms in a longitudinal design.[8] This design allowed us to describe incidence of these symptoms, and change in mood, and suicidal ideation as soldiers completed training and faced potential deployment to combat situations. Finally, we were interested in examining predictor variables of both baseline mental health symptoms and changes in mental health status with training. Specifically, we tested the hypothesis that female soldiers would have higher levels of depression, anxiety, and suicidal ideation and would be more likely to transition from subclinical to clinical levels of depression, anxiety, and suicidal ideation than male soldiers. Military status (active vs. reserve) was also expected to predict mental health status, with reservists less likely to have mental health symptoms than active duty soldiers. Other exploratory analyses examined age of soldier, previous military experience, education, and income as predictors of baseline mental health symptoms and changes with training.

MATERIALS AND METHODS

Study sample

Participants were composed of the first 18 companies of soldiers ($n = 3,792$) who participated in the randomized clinical

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trial on prevention of low back pain in the military (POLM).[8] These soldiers entered the combat medic 12-week Advanced Individual Training (AIT) program at Fort Sam Houston, Texas. Research staff at Fort Sam Houston, Texas introduced the study to individual companies of soldiers. Soldiers were screened for eligibility, and informed consent was obtained, as appropriate. For 12 consecutive months soldiers were screened for eligibility according to the following inclusion/exclusion criteria.

Inclusion criteria

— Ages 18 (or emancipated minor that is 17 years old) to 35 years old.
— Participating in combat medic military occupational specialty (MOS) training.
— English speaking and reading.

Exclusion criteria

— Prior history of low back pain (LBP) (operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the subject to seek health care) or previous medical history for any prior surgery for LBP.
— Currently seeking medical care for LBP.
— History of degenerative joint disease, arthritis, spine trauma or vertebral fractures, and/or spondylolisthesis.
— Currently unable to participate in physical fitness training due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand.
— History of fracture (stress or traumatic) in proximal femur and/or pelvis.
— Currently pregnant.
— Previous failure of AIT.

Dependent variables

The dependent variables for the study included depression, anxiety, and suicidal ideation. Their measurement is described below.

1. The Beck Depression Inventory (BDI), a 21-question multiple-choice self-report inventory, was used to measure the severity of depression. A total score for the BDI is calculated by summing the score for each item. Scores can range from 0 to 63. Soldiers who scored 15 or higher were classified as clinically depressed.
2. Soldiers who chose answers 1–3 for Question 9 of the BDI were designated as having suicidal ideation. Conversely, those who chose answer 0 were designated as not suicidal.
3. For anxiety, State Trait Anxiety Inventory (STAI) form Y-2 was used. The STAI yields summary scores ranging from 0 to 80. A total score of 46 or above was classified as clinically significant anxiety.

All three dependent variables were measured two times: at intake and at 12-week follow-up. A soldier was designated "worsened" if (s)he changed from not depressed to depressed and similarly for changing from subclinical anxiety to clinically significant anxiety and changing from not suicidal to suicidal ideation. Individuals who endorsed suicidal ideation were immediately referred with an accompanying soldier to base mental health services for a more complete evaluation. Data from these encounters were not available to the study personnel.

Independent variables

This study investigated three military related factors: (1) how long a soldier has been enlisted in the Army (time in Army: <1 year, 1–3 years, >3 years), (2) whether a soldier has previously been in the Navy (including Marines) or the Air Force (Navy or Air Force: yes, no), and (3) whether a soldier is a full-time active duty service member (active duty: yes, no).

Sociodemographic variables

Variables of interest and for risk adjustment in our final models included age (continuous), gender (female, male), race (white or Caucasian, others), highest level of education (education: college or more, high school or less), and approximate household income (income: $35,000 or more, less than $35,000).

Statistical analysis

All data were analyzed using SAS version 9.1. First, descriptive statistics were obtained on the sociodemographic and clinical variables. Second, generalized linear mixed models were fitted for the dichotomous outcomes on depression, anxiety, and suicidal ideation, including a random effect of company for the dependency of soldiers within the same unit and adjusting for the sociodemographic factors discussed above. In addition, we have fitted linear mixed models for the continuous depression and anxiety scores to estimate the effects of independent variables. The level of statistical significance was set at 0.05.

RESULTS

Among the 3,792 soldiers enrolled in the POLM study in the first three rounds, 72% were white or Caucasian, 71% were male, 53% had college or more education, 18% had $35,000 or more household income, 84% had been enlisted in the Army for less than 1 year and 9% for 1–3 years, 3% had previously been in the Navy (Marines) or the Air Force, and 59% were full-time active duty service members (Table I). The study population had a mean age of 22 years (SD = 4.39). Distributions of these variables were nearly the same for the 2,931 soldiers who remained at 12-week follow-up, suggesting limited potential of bias from soldiers who did not complete the follow-up assessment.

Table II showed that, at time of intake, 10.39%, 15.51%, and 4.11% of soldiers had depression, anxiety, and suicidal

ideation, respectively; and these percentages increased to 12.18%, 20.31%, and 5.70% at time of follow-up. In addition, 7.71%, 11.36%, and 3.99% of soldiers worsened in the three outcomes, respectively. Table II also showed that soldiers who are female, with high school or less education or with less than $35,000 income, had higher percentages of symptoms at both times of intake and of follow-up.

Table III presents the results of generalized linear mixed models for the dichotomous outcomes on depression, anxiety, and suicidal ideation. Compared with soldiers enlisted more than 3 years in the Army, the odds of having depression at time of intake were 0.47 times for those enlisted 1–3 years; similarly the odds of having depression and anxiety at time of intake were 0.52 and 0.60 times for those enlisted less than 1 year. Also, those who had not previously been in the Navy (Marines) or the Air Force had 0.56 times odds of having depression at the time of intake compared to their counterparts. These differences were not significant at the time of follow-up. In addition, the full-time active duty service members had 1.22 times and 1.57 times odds of anxiety and suicidal ideation at time of follow-up and 1.90 times odds of becoming worse in suicidal ideation, compared to those from a Reserve or National Guard unit.

Our results also show that female soldiers had significantly higher risk in the outcomes. More specifically, the odds of having depression at intake, depression at follow-up, or worsening depression for female soldiers were 1.73, 1.64, and 1.62 times compared to males; similarly the odds ratios of having anxiety at intake, anxiety at follow up, or worsening anxiety were 1.39, 1.49, and 1.36, respectively. Other factors significantly related to the outcomes were that older age was associated with lower odds of depression and anxiety and college or more education was associated with lower odds of anxiety at time of follow-up.

TABLE I. Sociodemographic and Military Characteristics of the Study Sample

Factors	Intake		Follow-up	
	n	%	*n*	%
Race				
Other		28	757	26
Caucasian	2,743	72	2,174	74
Gender				
Female	1,103	29	849	29
Male	2,689	71	2,082	71
Education				
College or higher	2,028	53	1,631	56
High school or lower	1,764	47	1,300	44
Income				
≥$35,000	665	18	521	18
≤$35,000	3,118	82	2,404	82
Time in Army				
1–3 years	322	9	268	9
<1 year	3,199	84	2,458	84
>3 years	269	7	203	7
Navy/Air Force				
No	3,668	97	2,849	97
Yes	124	3	82	3
Active Duty				
Yes	2,254	59	1,688	58
No	1,538	41	1,243	42
Age (mean [SD])	21.98	4.39	22.00	4.38
Total	3,792	100	2,931	100

TABLE II. Percentages of Soldiers Who Had Depression (*D*%), Anxiety (*A*%), and Suicide Attempt (*S*%)

Factors	Intake				Follow-up				Became Worse			
	n	D%	A%	S%	*n*	D%	A%	S%	*n*	D%	A%	S%
Race												
Other	1,049	9.53	14.68	4.48	757	10.96	18.40	6.08	757	6.87	9.86	3.96
Caucasian	2,743	10.72	15.82	3.97	2,174	12.60	20.97	5.57	2,174	8.00	11.89	4.00
Gender												
Female	1,103	14.05	18.59	4.62	849	15.90	24.56	6.01	849	10.25	13.40	4.12
Male	2,689	8.89	14.24	3.90	2,082	10.66	18.57	5.57	2,082	6.68	10.53	3.94
Education												
College or higher	2,028	9.42	13.61	3.94	1631	10.73	18.02	5.46	1,631	7.17	10.69	3.80
High school or lower	1,764	11.51	17.69	4.31	1300	14.00	23.18	6.00	1,300	8.38	12.20	4.23
Income												
≥$35,000	665	8.57	13.53	2.86	521	11.71	17.05	4.80	521	9.21	10.73	4.03
≤$35,000	3,118	10.81	15.97	4.39	2,404	12.31	21.02	5.91	2,404	7.40	11.48	3.99
Time in Army												
1–3 years	322	10.25	18.01	6.52	268	14.55	17.16	6.72	268	9.33	6.72	2.99
<1 year	3,199	10.16	15.04	3.94	2,458	12.25	20.97	5.86	2,458	7.73	12.12	4.27
>3 years	269	13.38	17.84	3.35	203	8.37	16.18	2.46	203	5.42	8.33	1.97
Navy/Air Force												
No	3,668	10.31	15.57	4.14	2,849	12.32	20.44	5.65	2,849	7.83	11.38	3.97
Yes	124	12.90	13.71	3.23	82	7.32	15.66	7.32	82	3.66	10.84	4.88
Active duty												
Yes	2,254	10.29	15.17	3.99	1,688	12.86	21.72	6.58	1,688	7.94	12.34	4.98
No	1,538	10.53	15.99	4.29	1,243	11.26	18.38	4.51	1,243	7.40	10.03	2.65
Total	3,792	10.39	15.51	4.11	2,931	12.18	20.31	5.70	2,931	7.71	11.36	3.99

TABLE III. Results of Generalized Linear Mixed Models for the Dichotomous Outcomes on Depression, Anxiety, and Suicidal Ideation

Effects	Intake			Follow-up			Became Worse		
	Odds Ratio	95% CI	P value	Odds Ratio	95% CI	P value	Odds Ratio	95% CI	P value
Depression									
Age	0.94	0.91 0.97	0.0002	0.97	0.94 1.01	0.0943	0.99	0.96 1.03	0.7131
Gender, female	1.73	1.39 2.16	<0.0001	1.64	1.30 2.08	<0.0001	1.62	1.22 2.15	0.0010
Race, others	0.85	0.67 1.08	0.1810	0.83	0.64 1.08	0.1630	0.81	0.58 1.12	0.1947
Education, college or higher	0.89	0.71 1.12	0.3275	0.79	0.62 1.01	0.0628	0.84	0.63 1.13	0.2585
Income ≥$35,000	0.87	0.63 1.18	0.3581	1.11	0.81 1.52	0.5066	1.40	0.98 2.00	0.0643
Time in Army 1–3 years	0.47	0.27 0.80	0.0058	1.45	0.77 2.73	0.2464	1.62	0.75 3.47	0.2170
Time in Army <1 year	0.52	0.35 0.77	0.0011	1.22	0.72 2.07	0.4604	1.32	0.70 2.52	0.3923
Navy/Air Force, no	0.56	0.32 0.97	0.0401	1.35	0.57 3.16	0.4951	1.96	0.60 6.34	0.2625
Active duty, yes	1.02	0.82 1.28	0.8529	1.26	0.99 1.61	0.0566	1.18	0.88 1.58	0.2712
Anxiety									
Age	0.94	0.91 0.97	<0.0001	0.97	0.94 1.00	0.0183	0.99	0.96 1.02	0.6044
Gender, female	1.39	1.15 1.68	0.0008	1.49	1.22 1.81	<0.0001	1.36	1.06 1.74	0.0151
Race, others	0.90	0.74 1.11	0.3252	0.83	0.67 1.02	0.0788	0.78	0.59 1.03	0.0763
Education, college or higher	0.86	0.71 1.05	0.1347	0.80	0.66 0.98	0.0272	0.87	0.68 1.12	0.2750
Income ≥$35,000	0.96	0.74 1.24	0.7458	0.90	0.69 1.17	0.4354	1.00	0.72 1.38	0.9811
Time in Army 1–3 years	0.65	0.41 1.02	0.0610	0.84	0.50 1.41	0.5042	0.71	0.35 1.45	0.3447
Time in Army <1 year	0.60	0.42 0.85	0.0043	1.10	0.73 1.65	0.6428	1.34	0.79 2.27	0.2730
Navy/Air Force, no	0.85	0.50 1.45	0.5484	1.01	0.55 1.86	0.9806	0.87	0.43 1.79	0.7082
Active duty, yes	1.00	0.82 1.20	0.9573	1.22	1.00 1.48	0.0456	1.19	0.93 1.52	0.1584
Suicidal Ideation									
Age	0.97	0.92 1.02	0.1812	0.96	0.92 1.01	0.1263	0.97	0.92 1.03	0.3135
Gender, female	1.13	0.80 1.61	0.4863	1.08	0.76 1.52	0.6828	1.06	0.70 1.60	0.7901
Race, others	1.13	0.79 1.61	0.5040	1.12	0.79 1.60	0.5283	0.99	0.65 1.52	0.9662
Education, college or higher	1.08	0.76 1.53	0.6736	1.06	0.76 1.50	0.7295	0.99	0.66 1.48	0.9660
Income ≥$35,000	0.70	0.42 1.16	0.1661	0.90	0.56 1.43	0.6396	1.14	0.68 1.92	0.6278
Time in Army 1–3 years	1.82	0.76 4.34	0.1775	2.71	0.96 7.64	0.0596	1.52	0.44 5.30	0.5125
Time in Army <1 year	1.10	0.52 2.32	0.8127	2.04	0.81 5.11	0.1307	1.89	0.67 5.31	0.2264
Navy/Air Force, no	1.03	0.37 2.88	0.9585	0.58	0.24 1.39	0.2236	0.65	0.23 1.87	0.4222
Active duty, yes	0.99	0.70 1.39	0.9567	1.57	1.11 2.22	0.0113	1.90	1.24 2.92	0.0034

The above findings were consistent with the results of linear mixed modeling of the continuous depression and anxiety scores. Table IV shows that, compared with soldiers enlisted more than 3 years in the Army, those enlisted less than 1 year were 1.30 points lower in the mean anxiety at time of intake, but 1.08 points higher in the mean depression change and 2.30 points higher in the mean anxiety change. These models also showed that female soldiers had a significantly higher level of depression and anxiety at time of intake and follow-up. Once again, older age was associated with less depression and anxiety at intake and at follow-up; while college or more education was associated with less depression at follow-up and less anxiety at both times. However, it should be noted that the sociodemographic and military factors together explained less than 3% of total variations in each of the three outcomes.

DISCUSSION

This study represents one of the few prospective, predeployment investigations of depression, suicidal ideation, and anxiety in the military. Unique features of the study include the investigation of the change in negative mood associated with AIT and the predictors of negative mood and change in mood in a military population. The rising incidence of mental health issues in military personnel, most likely the result of recent conflicts, highlights the need to investigate predisposing factors associated with mental health risk and the effects of training on mental health symptoms.

Our results suggest that at the time of entry into AIT, a substantial number of soldiers in training to become combat medics showed clinically significant levels of depression (10.4%) and anxiety (15.5%). In addition, over 4% endorsed suicidal ideation. These rates are relatively consistent with those associated with returning veterans[4] and entry-level military personnel.[1] Rates of suicide or prevalence of suicidal ideation involving the current military conflicts are not readily available and any direct comparisons of rates of suicidal ideation with suicide attempts or completed suicides should be made with caution. However, suicide ideation prevalence rates as high as 30% have been reported in deployment settings,[9] while suicide rates in Navy and Marine personnel ranged from 10 to 16 per 100,000 for the years 1999–2001.[10] The latter estimate of actual suicide rate in Navy and Marine personnel occurred in nonwartime deployment. The suicidal ideation reported in the present study is less than that reported in deployment settings; the increase in suicidal ideation at the end of AIT may reflect an increase associated with the possibility of impending deployment to combat, thus reflecting

TABLE IV. Results of Linear Mixed Models for the Continuous Outcomes on Depression and Anxiety

	Intake			Follow-up			Change		
	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value
Depression									
Intercept	8.65	1.04	<0.0001	8.14	1.39	<0.0001	0.59	1.25	0.6414
Age	−0.09	0.03	0.0011	−0.09	0.04	0.0189	0.01	0.03	0.8517
Gender, female	2.11	0.24	<0.0001	1.72	0.31	<0.0001	−0.15	0.28	0.5930
Race, others	0.05	0.24	0.8302	−0.44	0.32	0.1669	−0.59	0.29	0.0403
Education, college or higher	−0.09	0.23	0.7104	−0.61	0.30	0.0449	−0.68	0.27	0.0128
Income ≥$35,000	0.23	0.29	0.4334	0.21	0.38	0.5859	0.06	0.34	0.8632
Time in Army 1–3 years	−0.51	0.57	0.3683	0.78	0.74	0.2871	1.02	0.66	0.1230
Time in Army <1 year	−0.10	0.43	0.8215	0.74	0.57	0.1977	1.08	0.52	0.0368
Navy/Air Force, no	−0.88	0.61	0.1506	−0.65	0.86	0.4517	−0.65	0.78	0.4024
Active duty, yes	0.08	0.23	0.7230	0.57	0.30	0.0532	0.41	0.27	0.1215
Anxiety									
Intercept	42.78	1.44	<0.0001	42.81	1.87	<0.0001	0.28	1.52	0.8530
Age	−0.21	0.04	<0.0001	−0.16	0.05	0.0015	0.05	0.04	0.2500
Gender, female	1.72	0.33	<0.0001	1.87	0.42	<0.0001	0.44	0.34	0.1958
Race, others	−0.22	0.33	0.5110	−0.55	0.44	0.2045	−0.32	0.35	0.3615
Education, college or higher	−1.10	0.32	0.0005	−1.23	0.41	0.0027	−0.34	0.33	0.3151
Income ≥$35,000	−0.43	0.41	0.2875	−0.91	0.52	0.0809	−0.31	0.42	0.4645
Time in Army 1–3 years	−1.50	0.78	0.0565	−0.44	0.99	0.6548	1.08	0.81	0.1798
Time in Army <1 year	−1.30	0.60	0.0312	0.35	0.78	0.6548	2.30	0.63	0.0003
Navy/Air Force, no	−0.86	0.85	0.3106	−2.40	1.17	0.0397	−1.72	0.95	0.0694
Active duty, yes	0.04	0.31	0.9034	0.45	0.40	0.2629	0.26	0.32	0.4136

a continuum from nonwartime, to predeployment, to combat deployment.

Soldiers with less experience (shorter military service, no other service history) were slightly less likely to have clinically significant depression. However, duration of military service was not a significant predictor of depression or anxiety at the end of AIT. Examination of the changes within each group suggests that initial distress increased for those with less experience, while those with previous military history adjusted better (depression decreased) to the impending deployment as AIT progressed.

A different pattern emerged at post-AIT. Full-time active duty service members were more likely to have clinically significant depression and anxiety, as well as suicidal ideation, at the end of AIT. One potential explanation is that active duty personnel may have had greater experience with combat stressors and thus had higher anticipated distress as imminent deployment approached. The increased rate of distress in this group argued against a preventive function of AIT. The design of this study prevents definitive conclusions about the effects of AIT, but these speculations suggest further investigation with appropriate control for type of training might be fruitful.

Women were more likely to be depressed and anxious and to transition from subclinical to clinical levels of distress than were men. These findings are generally consistent with the larger literature on sex differences in negative affect.[7] As the number of women in the military increases, so does the importance of recognizing this increased risk. Increased age and greater education appeared to be somewhat protective

and were associated with decreased risk of depression and anxiety. However, these effects were not consistently observed at all time points and appeared relatively small in magnitude.

The same general pattern of results was observed whether the outcome variables were treated as dichotomous (clinically significant or not) or continuous, suggesting that the findings are relatively stable and not an artifact of the specific clinical cutoffs employed for this particular analysis. Overall, when considered as continuous variables, the magnitudes of observed differences during AIT are small and probably not clinically significant. The mean values for depression and anxiety are well below clinical cutoffs associated with a diagnosis of depression or anxiety, which may be a reflection of a general reticence of military personnel to report mental health symptoms.[11]

There are a number of limitations to this study. The study was not originally designed to assess trends in mental health issues in the military. The parent study was designed to test hypotheses about intervention to prevent back pain in military personnel and included the mood measures as predictors and descriptive data for that purpose. Because this report represents a secondary, exploratory analysis, a number of potential explanatory variables were not available for analysis. Furthermore, there was no experimental manipulation (e.g., treatment) related to negative mood, and the resulting data are correlational in nature with all the associated limitations about causality inferences. Our sample also appears to be relatively highly educated (53% with college education) and therefore combat medics may not be representative of the general army

population on that variable. This fact is especially important given that education is associated with lower rates of distress in this data set.

In summary, these data are consistent with reports of depression, anxiety, and suicidal ideation in military personnel. We have identified both demographic (i.e., age, sex) and military-specific predictors (i.e., duty status, history of military service) of psychological distress in soldiers undergoing combat medic training. These longitudinal data add to the existing literature by suggesting that as possible combat deployment is imminent, distress increases were also evident. AIT may be a time when preventive measures could be implemented or more tailored to the identified predictors. Further research designed to specifically investigate the identified predictors in other military populations, and with specific interventions, appear warranted. These could include better diagnostic criteria for depression and anxiety (particularly PTSD), longer follow-up to include suicide attempt data, a greater diversity of comparison groups/cohorts, and designs better able to infer causal relationships.

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Study protocol

Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009)

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Abstract

Background: There are few effective strategies reported for the primary prevention of low back pain (LBP). Core stabilization exercises targeting the deep abdominal and trunk musculature and psychosocial education programs addressing patient beliefs and coping styles represent the current best evidence for secondary prevention of low back pain. However, these programs have not been widely tested to determine if they are effective at preventing the primary onset and/or severity of LBP. The purpose of this cluster randomized clinical trial is to determine if a combined core stabilization exercise and education program is effective in preventing the onset and/or severity of LBP. The effect of the combined program will be compared to three other standard programs.

Methods/Design: Consecutive Soldiers participating in advanced individual training (AIT) will be screened for eligibility requirements and consented to study participation, as appropriate. Companies of Soldiers will be randomly assigned to receive the following standard prevention programs; a core stabilization exercise program (CSEP) alone, a CSEP with a psychosocial education (PSEP), a traditional exercise (TEP), or a TEP with a PSEP. Proximal outcome measures will be assessed at the conclusion of AIT (a 12 week training period) and include imaging of deep lumbar musculature using real-time ultrasound imaging and beliefs about LBP by self-report questionnaire. We are hypothesizing that Soldiers receiving the CSEP will have improved thickness of selected deep lumbar musculature (transversus abdominus, multifidi, and erector spinae muscles). We are also hypothesizing that Soldiers receiving the PSEP will have improved beliefs about the management of LBP. After AIT, Soldiers will be followed monthly to measure the distal outcomes of LBP occurrence and severity. This information will be collected during the subsequent 2 years following completion of AIT using a web-based data entry system. Soldiers will receive a monthly email that queries whether any LBP was experienced in the previous calendar month. Soldiers reporting LBP will enter episode-specific data related to pain intensity, pain-related disability, fear-avoidance beliefs, and pain catastrophizing. We are hypothesizing that Soldiers receiving the CSEP and PSEP will report the longest duration to first episode of LBP, the lowest

frequency of LBP, and the lowest severity of LBP episodes. Statistical comparisons will be made between each of the randomly assigned prevention programs to test our hypotheses related to determining which of the 4 programs is most effective.

Discussion: We have presented the design and protocol for the POLM trial. Completion of this trial will provide important information on how to effectively train Soldiers for the prevention of LBP.

Trial registration: NCT00373009

Background

Low back pain (LBP) is one of the most common forms of chronic pain [1,2] and is a significant cause of disability and cost in society [3-6]. Chronic LBP substantially influences the capacity to work and has been associated with the inability to obtain or maintain employment [5] and lost productivity [6]. Specific to the United States military, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually [7]. Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury [8], and LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars [9]. Reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs [10]. Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur [11]. Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. This cluster randomized clinical trial incorporates a combination of primary and secondary prevention strategies for limiting the occurrence and severity of LBP for active duty Soldiers in the U. S. Army.

Primary prevention

Theoretically, primary prevention would be the most effective manner to reduce disability from LBP; however, the current scientific literature does not support commonly used methods. For example, randomized clinical trials in occupational settings have demonstrated the ineffectiveness of commonly used primary prevention strategies such as back schools, lumbar supports, and ergonomic interventions [12,13]. Despite this lack of evidence, efforts continue to investigate primary prevention

interventions because of the obvious benefits of reducing LBP before it occurs. A recent review article suggests that future research related to primary prevention should focus on exercise programs, as they may offer the greatest potential for reducing disability from LBP [12]. Core stabilization exercise programs (CSEP) may be a good choice for primary prevention studies because biomechanical, anatomical, and clinical studies provide evidence that core stabilization is an effective intervention [14-16].

Biomechanical and anatomical evidence supporting core stabilization

Core muscles attached to the spine such as the transversus abdominus, multifidus, and the erector spinae play a key supportive role that contribute to the ability of the lumbar spine to withstand loading [17,18]. As an example, the transversus abdominus, one of the deep abdominal muscles, stabilizes the spine by forming a corset or rigid cylinder around the spine. Recent evidence supports a feed-forward postural control role for the transversus abdominus as it relates to limb movement [19-23]. Hodges et al [19-21,23] demonstrated that transverses abdominus muscle activation occurred prior to limb movement (regardless of directions) in asymptomatic adults. However, in patients with LBP, there is a delay in activation of transversus abdominus contraction relative to the primary muscles of the limb [24-26], suggesting that people with LBP lack optimal stability of the spine prior to activities requiring limb movements.

The multifidi are small intrinsic muscles that function as the primary intersegmental stabilizers of the spine [17]. Poor endurance of the multifidus is a predictor of increased recurrence of LBP. Further, multifidus atrophy and decreased muscular activity tends to occur on the side of symptoms [27-29]. The magnitude of atrophy has also been linked with poor outcomes following laminectomy surgery [30]. Furthermore, the multifidi do not automatically recover full strength and endurance after the first episode of LBP unless specific rehabilitation is done [31]. Hides et al [15,27,31] demonstrated that patients with >30% discrepancy in the cross-sectional area of the multifidus muscle are at an increased risk for having recurrent LBP unless treated with a CSEP.

The erector spinae (longissimus thoracis and iliocostalis lumborum) primarily produce extensor force needed for lifting but also stabilizes the spine. McGill has shown that the pars lumborum portions of these muscles are able to produce significant torque moments around all three orthopedic axes of motion [32], while Cholewicki demonstrated an antagonistic co-activation of trunk flexors and extensors occurs around the neutral spine in healthy subjects [33]. This co-activation increased in response to addition of an external load. In addition, Lee et al [34] found that, in a cohort of subjects followed for five years, the development of LBP was associated with lower levels of extensor strength compared to flexor strength. The convergence of these findings supports the need to further examine the effectiveness of exercise programs that target these muscles in preventing LBP.

Clinical evidence supporting core stabilization

Treatment and prevention exercise programs for LBP that have been reported in the literature commonly involve muscles involved in core stabilization such as the transversus abdominus, multifidi, and erector spinae muscles [15,16,35]. The fundamental component of these exercise programs is that they improve the neuromuscular activation and control of the targeted muscles. Reports in the literature have also highlighted that these programs may be an effective way to reduce disability from LBP. For example, a randomized clinical trial demonstrated that performance of a CSEP emphasizing activation of the transversus abdominus caused fewer recurrences of LBP 3 years following treatment for first time LBP [15]. Individuals with a >30% discrepancy in the cross-sectional area of the multifidus who completed a specific CSEP experienced 50% fewer recurrences of LBP at one year and 40% fewer recurrences at three years after treatment compared to individuals who received standard of care medical treatment [15].

The lack of core stabilization has been identified as a potential predictor of an individual's risk of developing recurrent LBP [36,37], further increasing the impetus for incorporating CSEP into routine physical training programs across the United States Army. While these assertions regarding CSEP and LBP prevention are promising, they have not been rigorously tested in clinical trials involving healthy Soldiers. Differences in muscle training are important to consider because TEP training focuses on muscles (i.e. rectus abdominus and oblique abdominals) not consistently supported by biomechanical and anatomical evidence [19,24,38,39]. In fact, a clinical trial suggests that exercises included in a TEP were ineffective at preventing LBP [40]. Therefore, it is not known if performance of CSEP effectively prevents LBP when compared to a traditional exercise program (TEP) commonly implemented in physical training.

Secondary prevention

The scientific literature has also investigated secondary prevention as a strategy to reduce disability from LBP because effective primary prevention strategies are currently lacking [11]. Secondary prevention strategies have met with some success, and two consistent themes have developed. The first theme is that psychological factors play a significant role in the development of chronic disability from LBP. Prospective studies involving patients with acute LBP have consistently demonstrated that when compared to demographic or physical factors, psychological factors are the strongest predictors of chronic disability from LBP [41,42]. The second theme is that early interventions that address these psychological factors result in decreased disability from LBP [43-45].

Psychological model for the development of chronic low back pain

Psychological models are commonly used to explain one manner in which chronic disability develops from LBP [46,47] and one specific model is the Fear-Avoidance Model (FAM) [48]. This model proposed that *fear-avoidance beliefs* and *pain catastrophizing* are the primary psychosocial factors involved in the development and maintenance of chronic symptoms. Fear-avoidance beliefs are comprised of an individual's pain experiences, present stress level, pain behavior, and certain personality traits [49]. Fear-avoidance beliefs detail an individual's fear of pain and re-injury specific to LBP and the belief as to whether physical activity should be maintained while experiencing LBP [49]. Pain catastrophizing is a negative, multidimensional construct comprised of rumination, helplessness, and pessimism cognitions [50]. Pain catastrophizing is related to the belief that the experienced pain will inevitably result in the worst possible outcome [50].

Collectively, these psychosocial factors determined the response to an episode of LBP along a continuum from confrontation to avoidance. A confrontation strategy (low levels of fear-avoidance beliefs and pain catastrophizing) is viewed as an adaptive response, enabling the individual to return to normal vocational and social activities. An avoidance strategy (high levels of fear-avoidance beliefs and pain catastrophizing) is viewed as a maladaptive response. The consequences of an avoidance strategy are theorized to be both psychological (hyperalgesia) and physical (chronic disability and reductions in physical performance). Furthermore, continuation of an avoidance response contributes to the pain experience in a deleterious manner by making it more likely to maintain high levels of pain-related fear and pain catastrophizing.

Clinical evidence supporting psychosocial education programs

Fear-avoidance beliefs and pain catastrophizing were strongly associated with pain intensity and disability in patients with chronic LBP [51-55]. Longitudinal studies have demonstrated that fear-avoidance beliefs and pain catastrophizing are also precursors to the development of chronic disability [41,56-58]. As a result, it has been hypothesized that early reduction of fear-avoidance beliefs and pain catastrophizing is an important way to reduce development of chronic LBP.

Psychosocial education programs (PSEP) that reduce fear-avoidance beliefs and pain catastrophizing have been described in the literature [44,45,59,60]. These educational programs differ from traditional educational approaches in that they de-emphasize the anatomical cause of LBP (as it often cannot be determined), encourage the patient to take an active role in his recovery, provide evidence-based information on LBP management and outcome, teach the patient to view back pain as a common (i.e. not a serious disease) condition, and instruct the individual on the importance of maintaining positive attitude and coping styles (i.e. limiting fear-avoidance beliefs and pain catastrophizing).

Randomized clinical trials and quasi-experimental designs provide consistent evidence that PSEP's decrease maladaptive beliefs and coping styles in healthy individuals and patients experiencing LBP [43,44,61,62]. Furthermore, early evidence from randomized clinical trials suggests that psychological and physical LBP severity (i.e. fear-avoidance beliefs, coping strategies, pain intensity and/or pain-related disability) can be decreased when PSEP's are implemented in individuals experiencing LBP [43-45]. This evidence is promising, as it suggests that severity of LBP can be favorably modified with a PSEP. Although a PSEP delivered via public service announcements has been investigated in healthy individuals and found to decrease beliefs associated with LBP [62], no research has determined if PSEPs are effective at reducing the occurrence or severity of LBP when administered to healthy individuals.

Summary and purpose

The accumulated evidence supports the potential of CSEP and PSEP for prevention of LBP. Early evidence supports the effectiveness of these combined programs for reducing future disability in patients already experiencing LBP [44,45]. However, the effect of early implementation (i.e. in healthy individuals before the onset of LBP) of combining CSEP and PSEP has not been previously investigated in a large-scale, controlled study. The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combination of CSEP and PSEP is effec-

tive in limiting the onset of LBP and/or the severity of LBP. The effect of this combined program will be compared to three other standard programs.

Methods/Design

The institutional review boards at the Brooke Army Medical Center (Fort Sam Houston, Texas) and the University of Florida (Gainesville, FL) have granted approval for this project. Figure 1 provides an overview of the proposed study design.

Subjects

We will be recruiting consecutive Soldiers entering the combat medic 12-week advanced individual training (AIT) program at Fort Sam Houston, Texas. Soldiers will be screened for eligibility according to the following inclusion/exclusion criteria:

Inclusion criteria
• Ages 18 (or emancipated minor that is 17 years old) – 35 years old
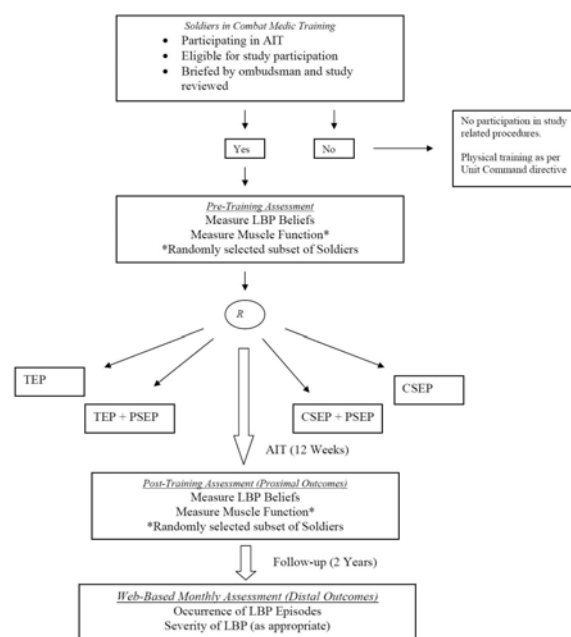
Figure 1
Proposed study design of the prevention of low back pain in the military (POLM) trial. LBP, low back pain; AIT, advanced individual training; CSEP, core stabilization exercise program; PSEP, psychosocial education program; TEP, traditional exercise program.

• Participating in combat medic military occupational specialty (MOS) training

• English speaking and reading

Exclusion criteria
• Prior history of LBP (defined as LBP that limited work or physical activity for greater than 48 hours or caused individual to seek healthcare)

• Currently seeking medical care for LBP

• Previous medical history including history of degenerative joint disease, arthritis, spine trauma or vertebral fractures, spondylolisthesis, and/or congenital spine disorders. This also includes any prior surgery for LBP

• Currently unable to participate in unit physical training due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand injury.

• History of fracture (stress or traumatic) in proximal femur and/or pelvis

• Currently pregnant (later pregnancy will not result in termination from the study, but it is an exclusion criteria at enrollment.)

• Have been rolled over from another Company participating in combat medic military occupational specialty (MOS) training

Research staff at Fort Sam Houston, Texas will introduce this study to Soldiers, screen them for eligibility, and obtain informed consent from Soldiers, as appropriate. The informed consent document will obtain permission from Soldiers to perform the study-related procedures and to contact them at their civilian address if any of the participants have been separated or discharged from active duty during the 2-year follow-up period. After providing informed consent, Soldiers will be issued a card with username, password, and information for accessing a secure website hosted by the University of Florida. Subjects will be monitored through all four stages of this trial (enrollment, intervention allocation, follow-up, and data analysis) in compliance with CONSORT guidelines [63]. For example, we will record reasons for a subject dropping out of the study during any stage of the trial and we will record all reasons for non-participation in the study to enable our ability to calculate an overall participation rate.

Randomization
We acknowledge the ideal study design to answer our research question would involve individual randomization of Soldiers to the 4 prevention programs. However,

individual randomization presents unique challenges in a military training environment that would seriously impede this study's feasibility. Military training environments require Soldiers to live in close quarters with other members of their unit, to facilitate optimal training and to foster esprit de corps. Soldiers function in teams during many of their training activities, including unit physical training. Specifically, we elected not to individually randomize to the prevention programs because a) it would potentially detract from unit cohesion, b) contamination of the treatment groups would be inevitable, and c) the administration of the study would be excessively burdensome for drill instructors leading unit physical training.

Therefore, we will utilize a cluster randomization strategy by randomly assigning company units, such that every Soldier in the company who consents to participation in the study completes the same prevention program. Cluster randomization has been effectively used in other investigations involving large samples of musculoskeletal injury prevention, adherence to quality indicators for prevention of cardiovascular disease, and the effect of a community-based intervention on maternal depression [64-66]. The cluster randomization schedule will be determined before recruitment begins and will be balanced.

Exercise programs
The Soldiers' drill instructors will receive comprehensive training in the study procedures prior to beginning the study to insure their proficiency in administering the standardized exercise programs. Drill instructors will be issued detailed pre-prepared training cards specific to each program and training information will also be available on a study-related web-site. These training cards will be used to ensure the proper administration of the training protocol for a particular company. Study personnel will be present at training times to ensure compliance with the assigned exercise program.

Traditional exercise program (TEP)
The TEP was selected from commonly performed exercises for the rectus abdominus and oblique abdominal muscles. These exercises are traditionally performed in the military environment and are commonly utilized to assess physical performance of Soldiers. Soldiers will be instructed to perform the exercises in a group setting under the direct supervision of their drill instructor. This exercise regiment consists of 5 exercises and each will be performed for 1 minute. The TEP will be performed daily, for a total dosage time of 5 minutes/day, 5 days per week. Having Soldiers perform the TEP in group physical training settings will help ensure compliance with the TEP.

Exercises in the TEP are widely utilized inside (and outside) the military for physical training purposes. These

exercises target the rectus abdominus and oblique abdominal muscles, which are not supported by the accumulated anatomical, biomechanical, and clinical evidence for preventing LBP [15,24,27,31,38,40]. Furthermore, the exercise prescription emphasizes quick activation, high load, and high repetitions with full movements of the trunk and this type of prescription does not match these muscles' function [38,67]. We believe the TEP will not effectively prevent LBP because it focuses on trunk musculature not highlighted in the LBP prevention literature and exercises muscles in a sub-optimal manner.

Core stabilization exercise program (CSEP)
The CSEP will consist of exercises from the accumulated evidence shown to selectively activate the transversus abdominus, multifidi, and erector spinae. Soldiers in this group will perform crunches in lieu of regular sit-ups. Soldiers will be issued photographs of the exercises with written instruction in technique. Then, Soldiers will be instructed to perform the exercises in a group setting under the direct supervision of the drill instructor. This exercise regiment consists of 5 exercises and each will be performed for 1 minute. The CSEP will be performed daily, for a total dosage time of 5 minutes per day, 5 days per week. Having Soldiers perform the CSEP in-group physical training settings will ensure compliance with the CSEP.

The CSEP was selected from current evidence previously discussed. [15,24,27,31,38,40] This literature demonstrates that these exercises increase activation of key core musculature. The exercise prescription for the CSEP follows a slow activation, low load principle with minimal trunk movements, that best matches these muscles' function, according to noted experts in the area [38,67] These exercises are also supported by the United States Army Physical Fitness Program's new doctrine, yet they have not been clinically tested for preventing LBP. We hypothesize the CSEP will effectively prevent LBP because it focuses on core musculature highlighted in the LBP prevention literature and exercises these muscles in an appropriate manner. Table 1 provides a brief comparison of the two exercise programs.

Psychosocial education program (PSEP)
We elected not to include a traditional education program in this trial, as prior studies consistently demonstrate traditional education does not favorably change LBP beliefs[44,61,62,68] The education program involves attending 1 educational session during the first week of AIT for randomly assigned soldiers. The session will involve an interactive seminar led by study personnel lasting approximately 45 minutes. The seminar will consist of a visual presentation that presently comprises evidence-based education for LBP.

Table 1: Comparison of traditional (TEP) and core stabilization exercise (CSEP) programs

Exercise	CSEP	TEP
Principle	Lower load, less repetitions	Higher load, more repetitions
Activation	Slower	Faster
Trunk movements	None to minimal	Full
Dosage	5 minutes/day	5 minutes/day
#1	Abdominal drawing-in maneuver crunch	Traditional sit-up
#2	Left and right horizontal side support	Sit-up with left trunk rotation
#3	Hip flexor squat ('wood-chopper')	Sit-up with right trunk rotation
#4	Supine shoulder bridge	Abdominal crunch
#5	Quadruped alternate arm and leg	Traditional sit-up

TEP, traditional exercise program; CSEP, core stabilization exercise program

The seminar will cover topics like the prognosis of LBP, stressing that anatomical causes of LBP are not likely, and emphasizing the importance of decreasing fear-avoidance beliefs and pain catastrophizing in response to LBP. Educational material about the natural course of low back pain will be included. After the seminar, Soldiers will be involved in a question and answer session led by study personnel. Finally, Soldiers will be issued *The Back Book* for their personal use. *The Back Book* is being used because we have prior experience with it and it has been demonstrated to reduce fear-avoidance beliefs [43,44]. Proper administration of the PSEP will be ensured by having study personnel lead the educational session for Soldiers assigned to receive PSEP.

Blinding
It is not possible to mask Soldiers in this study because they will actively participate in the randomly assigned training programs. Post-training physical examinations and real time ultra-sound imaging will be performed by personnel unaware of program assignment. Soldiers will be instructed not to discuss their group assignment with study personnel during post-training examinations unless there is an urgent reason to do so (e.g. for medical reasons).

Measures
Study related measures are separated into proximal outcome measures, consisting of self-report and physical measures (pre and post AIT), and distal outcome measures, consisting of LBP episode-related measures (2 years active duty).

Proximal outcome – self-report measures (pre and post training)
Physical and Mental Function
The Medical Outcomes Survey 12-Item Short-Form Health Survey (SF-12) will be used as a self-report of health status for physical and mental function. The derived physical component summary scale (PCS) and mental component summary (MCS) are believed to be a valid option to represent the eight domains of physical and mental components of health [69].

Negative Affect
The State-Trait Anxiety Questionnaire (STAI) will be used to measure negative affect from anxiety [70]. The Beck Depression Inventory (BDI) will be used to measure negative affect from depression [71-73].

Fear of Pain
The Fear of Pain Questionnaire (FPQ-9) will be used to measure fear about specific situations that normally produce pain [74-76].

LBP Beliefs
The Back Beliefs Questionnaire (BBQ) will be used to beliefs about management and outcome associated with LBP [61,77].

Proximal outcome – physical measures (pre and post training)
Randomly selected Soldiers (n = 20) from each company will undergo physical measures. This decision was made due to the time and expense associated with performing a physical examination and real-time ultrasound imaging on a sample this large.

Physical Impairment
Total lumbar flexion and straight leg raise from the physical impairment scale described by Waddell et al [78] will be used in this study. Range of motion measurements of bilateral hip internal and external rotation will be used. Additionally, 4 trunk endurance tests will be used for maintaining extensor, flexor, and bilateral side support positions.

Real-Time Ultrasound Imaging
All real-time ultrasound measurements of the deep trunk muscles will be obtained using a Sonosite 180 Plus (Sonosite Inc. Bothell, WA) with a 5 MHz curvilinear array for the lateral abdominal muscles and the posterior trunk muscles [79]. Ultrasound measurements of the lateral abdominal muscles (transversus abdominus, internal oblique, and external oblique) during the active straight leg test maneuver will be obtained following the techniques outlined by Teyhen et al [80] Symmetry measurements of the multifidi muscles will be performed as outlined by Hides et al [81].

Distal outcome – low back pain (LBP) episode-related measures
We will follow Soldiers for 2 years following graduation from AIT to record the number and the severity of LBP episodes experienced. Monthly emails containing a link to the University of Florida hosted POLM website will query Soldiers on whether they have experienced any LBP in the last calendar month, and if so, the Soldiers will be prompted to complete the information described below.

Compliance
Compliance to the Soldiers' randomly assigned exercise and education programs will be recorded for each month.

Onset of LBP
Soldiers will be queried whether they have experienced LBP in the last calendar month. If they have, Soldiers will be cued to answer following validated self-report questionnaires.

Disability
Self-report of low back-related disability will be assessed with the Oswestry Disability Questionnaire (ODQ), a scale originally described by Fairbank et al [82]. The ODQ that will be used in this study was modified from the original version by substituting a section regarding employment/home-making ability for the section related to sex life [83,84].

Pain
Patients will rate their pain intensity and unpleasantness using a numerical rating scale (NRS). The NRS consist of 11 points whose endpoints are designated as '0 – no pain sensation' and '10 – the most intense pain sensation imaginable.'

Fear-Avoidance Beliefs
The Fear-Avoidance Beliefs Questionnaire (FABQ) will be used to quantify fear-avoidance beliefs in this study [53].

Pain Catastrophizing
The Pain Catastrophizing Scale (PCS) will be used to quantify pain catastrophizing [85].

Data analysis
Demographic and baseline levels of clinical variables will be compared between the 4 cluster randomized groups using analysis of variance (ANOVA) for comparison of means and chi-square tests for comparison of proportions. Variables found to be significantly different between the training groups will be considered in the final analyses, in addition to prespecified covariates (gender, age, and physical impairment). Six analyses will be performed based on our pre-specified hypotheses. Primary outcomes will be analyzed with Poisson regression for occurrence of LBP and Cox regression for time to first epi-

sode of LBP. Secondary outcomes will be analyzed with MANOVA and ANOVA models. Based on Bonferroni adjustment, we will conduct each of the hypothesis tests two-sided at the 0.008 levels. All statistical analyses will be performed using the SAS software, version 9 (SAS Institute Inc, 1996).

Sample size estimation and power analysis
Company size and consent rate are expected to vary, so the following represent the assumptions used for a sample size estimation and power analysis. A total of 16 companies could potentially be randomly assigned to the 4 programs, with approximately 200 eligible Soldiers per company, and 75% are expected to provide consent for study participation. Our sample size estimation was based on determining the effect of the CSEP and PSEP on preventing the occurrence and severity of LBP episodes.

We expect that 33% Soldiers performing a prevention program will experience LBP compared to 51% for those in the control group [86]. For a group difference of such magnitude, a two-sided statistical test at 0.008 level should have more than 99% of power for 4 companies of soldiers. However, we will enroll up to 16 companies because only the Soldiers reporting LBP will be included in certain hypotheses. With 16 companies, we expect approximately 450 soldiers in the combined program and 675 soldiers in traditional program group to experience LBP. Data in Table 2 demonstrates the expected power to detect differences among Soldiers experiencing LBP using pilot estimates from George et al [44].

For our proximal outcomes, we will randomly sample Soldiers from each company. These Soldiers will be assessed by physical examination and with real-time ultrasound imaging to measure changes in specific core muscles during AIT. Our assumptions for power calculations were that statistical tests will be conducted at the 0.007 levels and we conservatively assumed that the differences in specific core musculature between Soldiers completing CSEP and those not completing CSEP in this study would be at least half the amount seen in the pilot estimates from Teyhen et al [80]. A sample size of 16 companies will provide more than 90% power as shown in Table 3.

Treatment of Soldiers not completing training protocol
There is approximately a 20% attrition rate for Soldiers not completing AIT. The reasons for attrition are varied, but can be broadly defined into medical, physical, personal, academic, or behavioral categories. Decisions regarding Soldier attrition are made by Commanding Officers, independent of the study investigators. Therefore, we have no direct influence on Soldier attrition rates. The consequence of attrition for the Soldier is that he or she joins another company and resumes AIT. The consequence of attrition for the proposed analysis plan is that the reassigned Soldier will likely be performing a different training protocol than original assigned. Therefore, such soldiers represent a potential internal validity threat to this study.

The following a priori decisions have been made to account for Soldiers that consented to study participation, but did not complete AIT. First, any Soldier completing less than 10-weeks of AIT will have the reason for attrition recorded, and will not be followed during active duty. Second, the reasons and rates of attrition will be compared between the 4 cluster randomized groups using chi-square tests for comparison of proportions. This approach will allow the investigators to protect the internal validity of the study, by ensuring Soldiers receiving multiple interventions of unknown duration are not followed during active deployment. This approach will also allow the investigators to determine if the attrition rates were consistent across companies throughout the length of the study.

Treatment of missing data
We will handle missing data values with a 3-step process. First, the dropout rates will be compared across the programs to assess systematic differences. Second, demographic and dependent variables will be examined for their relationship to dropout. Those variables related to dropout status will be used to impute missing values for use in the analyses described below (via Missing Items Analysis). This multiple imputation approach will be compared to a last observation carried forward approach, mixed models approach, or worst-case approach to missing data. In addition, we will analyze completers only, as a liberal estimate of treatment efficacy. Finally, compari-

Table 2: Power estimates for low back pain episode specific outcomes

Measure of LBP severity	Traditional program	Combined program	Power (16 companies)	Power (12 companies)
FABQ (physical activity)	13.5 (sd = 7.0)	10.1 (sd = 5.9)	100%	100%
FABQ (work)	12.3 (sd = 12.3)	9.7 (sd = 10.2)	86%	65%
ODQ	15.5 (sd = 17.9)	11.9 (sd = 10.0)	92%	77%

FABQ, Fear-avoidance beliefs questionnaire; ODQ, Oswestry disability questionnaire

Table 3: Power estimates for muscle imaging outcomes

Muscle measure (thickness)	TEP	CSEP	Power (16 Companies)
Transversus abdominus	1.5 (sd = 0.5)	2.0 (sd = 0.5)	100%
Erector spinae	31.0 (sd = 6.0)	34.5 (sd = 6.0)	90%
Multifidi (symmetry)	20.0% (sd = 6.0)	11.5% (sd = 6.0)	100%

TEP, traditional exercise program; CSEP, core stabilization exercise program

son of the completers vs. imputation analyses will yield an additional estimate of the effect of dropouts on hypothesis tests.

Discussion

We have presented the design and protocol for the POLM trial. We will train Soldiers with specific exercise and education programs and measure the occurrence and severity of LBP episodes over a 2-year period. Completion of this trial will provide important information on how to effectively train U.S. Soldiers for the prevention of LBP. Results of the POLM trial will be disseminated as soon as they are available.

Abbreviations

LBP, low back pain; AIT, advanced individual training; CSEP, core stabilization exercise program; PSEP, psychosocial education program; MOS, military occupational specialty; POLM, Prevention of low back pain in the military trial; FAM, Fear-avoidance model; TEP, Traditional exercise program; STAI, State-trait anxiety questionnaire; FPQ, Fear of pain questionnaire; BBQ, Back beliefs questionnaire; SF-12, Medical outcomes survey 12-item short-form health survey; PCS, Physical component summary scale; MCS, Mental component summary scale; ODQ, Oswestry disability questionnaire; NRS, numerical rating scale; FABQ, Fear-avoidance beliefs questionnaire; PCS, Pain catastrophizing scale

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

All authors read, edited, and approved the final version of the manuscript. SZG, JDC, DST, SSU, and MER were responsible for the initial conception of the research question, securing funding, supervising the protocol, and manuscript preparation. ACW and JLD were responsible for implementing study protocol and critically reviewing earlier versions of this manuscript.

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Title
Predictors of Web-based Response Rate in the Prevention of Low Back Pain the Military (POLM) Trial

Purpose/Hypothesis
Follow-up in clinical trials is essential to establish the validity of the findings. Achieving adequate response rates reduces the amount of bias and helps to insure that the findings can be generalized to the population of interest and more accurately inform clinical decision-making. Therefore, the purpose of this study was to examine the influence of psychological variables, health status, physical activity, injury status, attention/relationship effect, and demographic characteristics on one year response rates in the Prevention of Low Back Pain the Military (POLM) trial.

Subjects
Subjects included healthy Soldiers between 18-35 years of age participating in Advanced Individualized Training and enrolled in the Prevention of Low Back Pain in the Military (POLM) trial (n=4,295).

Materials/Methods
Twenty companies of Soldiers were cluster randomized to complete a traditional exercise program including sit-ups (TEP) with or without a psychosocial educational program (PSEP) or a core stabilization exercise program (CSEP) with or without PSEP. A subgroup of Soldiers (n=250) was randomized to receive a physical and ultrasound imaging (USI) examination of key trunk musculature. All Soldiers were encouraged to complete monthly surveys via email during the first year following completion of training to record incidence/severity of subsequent LBP episodes. Descriptive statistics of the demographic and clinical variables were obtained and compared between the responders and non-responders using two sample

t-tests or chi-square test, as appropriate. Generalized linear mixed models were subsequently fitted for the dichotomous outcomes to estimate the effects of independent variables and other explanatory variables. A random company effect was included in the models to accommodate for the correlation among Soldiers within the same company. The significance level was set at 0.05 a priori.

Results
The overall response rate was 18.9% (811 subjects). Non-responders and responders significantly differed in age, race, education, income, military status, length of service, depression, back beliefs, anxiety, health status, smoking history, BMI, and whether a Soldier received the physical/USI examination ($p<.05$). Income, time in army, depression, back beliefs, and health status became statistically non-significant after adjusting the previously stated factors. Lastly, the above findings were consistent with the results of a reduced model derived from a stepwise backward selection procedure that eliminates non-significant factors at alpha level of 0.10.

Conclusion
Response rate is significantly associated with psychological variables, demographic characteristics, and receiving individualized attention. Although the overall response rate is low compared to standard clinical trials, it is consistent with typical response rates observed in similar studies using web-based surveillance systems.

Clinical Relevance
Understanding which factors are associated with response rates can help to inform the design of clinical trials. Additional attention during a trial may improve response rates.

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Title
Effects of traditional sit-up training versus core stabilization exercises on short-term musculoskeletal injuries in US Army Soldiers: A cluster randomized trial (NCT00373009)

Purpose/Hypothesis
Despite the longstanding incorporation of traditional bent-knee sit-ups in US Army physical training, sit-up training increases lumbar spine loading, potentially increasing the risk of experiencing musculoskeletal (MSK) injuries and low back pain (LBP). "Core stabilization" exercises have been recommended as an alternative based on evidence demonstrating improved abdominal and trunk muscle strength without excessive spine loading and the potential for decreasing the incidence of LBP and lower extremity (LE) injuries. The purpose of this study was to explore the short-term effects of a core stabilization exercise program (CSEP) without sit-up training compared to a traditional exercise program (TEP) on musculoskeletal injury incidence and work restriction. We hypothesized that no differences would exist.

Number of Subjects
Subjects included Soldiers between 18-35 years of age participating in Advanced Individual Training (AIT) who had complete injury data available for analysis (n=1141).

Materials/Methods
Twenty companies of soldiers were cluster randomized to complete CSEP (10 companies of 542 Soldiers) or TEP (10 companies of 599 Soldiers). CSEP included exercises that target the transversus abdominus and multifidi musculature. TEP was comprised of exercises targeting the rectus abdominus, oblique abdominals, and hip flexor musculature. Research

staff recorded all injuries resulting in the inability to complete full duty responsibilities. Differences in the percentage of musculoskeletal injuries were examined with chi-square; independent samples t-tests were used to examine differences in the number of work restricted days.

Results
The mean age of subjects was 22.9±4.7 years. Of 1141 Soldiers who had complete injury data available for analysis, 511 (44.8%) Soldiers experienced a musculoskeletal injury during training that resulted in work restrictions. No differences existed in the percentage of those with musculoskeletal injuries. There was also no difference in work restricted days for musculoskeletal injuries overall or specific to the upper extremity. However, Soldiers completing TEP group who experienced a low back injury had more work restricted days (TEP=8.3±14.5; CSEP=4.2±8.0, P=0.083).

Conclusions
Musculoskeletal injury incidence was similar between the groups. There was marginal evidence that CSEP resulted in fewer work restricted days for low back injuries, potentially indicating that a protective benefit for CSEP might be observed over a longer time period once the full dosing of the intervention has been realized.

Clinical Relevance
CSEP does not result in increased MSK injuries and may result in fewer limited duty days for those with a low back injury.

Psychosocial Education Improves Low Back Pain Beliefs: Results from a Cluster Randomized Clinical Trial (NCT00373009)

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Purpose. The general population has a pessimistic view of LBP and evidence based information has been used to positively influence LBP beliefs in previously reported mass media studies. Since previous studies utilized non-randomized methodologies, there is a lack of randomized trials demonstrating these effects in primary prevention settings. This cluster randomized clinical trial investigated the effect of a psychosocial educational program (PSEP) on low back pain (LBP) beliefs for Soldiers completing military training.

Number of Subjects: Consecutive companies of Soldiers (n = 3,792) were recruited into this clinical trial.

Methods. Companies were cluster randomized to receive a PSEP or no education (CG). The PSEP consisted of an interactive seminar and Soldiers were issued the *Back Book* for reference material. LBP beliefs were assessed by the Back Beliefs Questionnaire (BBQ) before randomization and 12-weeks later. A linear mixed model was fitted for the BBQ change in continuous scale and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of greater than 2 points. Sensitivity analyses were performed to account for drop out.

Results. BBQ scores (potential range: 9 – 45) improved from baseline of 25.6±5.7 (mean±sd) to 26.9±6.2 for those receiving the PSEP, while there was a decline from 26.1±5.7 to 25.6±6.0 for those in the CG. These group differences were statistically significant (p<0.0001). The adjusted mean improvement for those receiving the PSEP was 1.74 points higher than those in the CG (p<0.0001). The adjusted odds ratio of BBQ improvement of greater than 2 points for those receiving the PSEP was 1.51 (95% CI = 1.22 – 1.86) times that of those in the CG. BBQ improvement was mildly associated with race, college education, and depression. Sensitivity analyses suggested minimal influence of drop out.

Conclusions. Soldiers that received the PSEP had an improvement in their beliefs related to the inevitable consequences of and ability to cope with LBP. The magnitude of improvement was clinically meaningful when compared to previous studies.

Clinical Relevance. Potentially maladaptive LBP beliefs can be positively altered by a group education program applied in a primary prevention setting.

Key Words: primary prevention, patient education, biopsychosocial, public health

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Title
Effects of sit-up training versus core stabilization exercises on sit-up performance: A cluster randomized trial (NCT00373009)

Purpose/Hypothesis
Despite the longstanding tradition of performing sit-ups in the US Army, it has been postulated that this exercise increases lumbar spine loading, potentially increasing the risk of injury and development of low back pain (LBP). To address these concerns, health professionals commonly recommend "core stabilization" exercises, which based on evidence improve abdominal and trunk muscle strength without excessive spine loading and may decrease the incidence of LBP while increasing performance. However, core stabilization exercise programs (CSEP) have not been widely adopted in the US Army because of the perceived deleterious impact on sit-up performance on the Army Physical Fitness Test (APFT). Therefore, the purpose of this study was to determine whether performing CSEP in lieu of traditional sit-ups has detrimental effects on APFT sit-up and push-up performance and pass rates.

Materials/Methods
Subjects included healthy Soldiers between 18-35 years of age participating in Advanced Individual Training (N=2616). Soldiers with a previous history of LBP or other serious condition that precluded participation in physical training were excluded. Companies of Soldiers were cluster randomized to receive traditional exercise program (TEP) or CSEP. TEP consisted of exercises that target the rectus abdominus, oblique abdominals, and hip flexor musculature. CSEP was comprised of exercises that target the transverus abdominus and multifidi musculature. Soldiers completed their exercise program during unit physical training 4 times per week for 12 weeks. Performance on the AFPT was assessed at baseline and 12 weeks. Descriptive statistics were calculated to summarize the data. Independent

variables were Group, Quartile, and Time. Dependent measures were scores and pass rates for sit-up, push-up, and overall APFT. A 2×4×2 repeated-measures ANOVA with pairwise comparisons using the Bonferroni inequality was performed to examine differences in the overall and sit-up scores. Differences in pass rates were assessed with a chi-square. The alpha-level was set to 0.05 a priori.

Results
The mean age of subjects was 21.9 ± 4.3 years of age. Both groups performed sit-ups outside of unit physical training at equal rates (TEP: 69.5% and CSEP: 65%, P=0.067). Both groups demonstrated significant improvements in their overall and sit-up score and pass rates over time (P<0.05). There were no significant between group differences in overall scores (P=0.142) or sit-up performance (P=0.543) on the APFT after 12 weeks of training. CSEP and TEP improved their sit-up pass rates by 5.6% and 3.9%, respectively (P<0.05). The NNT for CSEP was 56.

Discussion
CSEP did not have a detrimental impact on APFT scores or pass rates. There was actually a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP (3.9%). Therefore, incorporating CSEP into Army physical training does not increase the risk of suboptimal performance on the APFT.

Conclusion
A company with 400 Soldiers performing CSEP would actually result in 7 additional Soldiers progressing from a failure to a pass on the sit-up component of the APFT compared to TEP.

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The Influence of Sex, Height and Weight on Trunk Muscle Thickness and Endurance

Trunk muscle endurance may have an important role in the prevention and treatment of low back pain (LBP). Direct assessment of trunk muscle function is not feasible. Therefore, muscle morphometry has been used as an indirect measure. The purpose was to describe how sex, height, weight, and body mass index (BMI) influence trunk muscle thickness and endurance times and to provide reference data for trunk morphometry in Soldiers.

Soldiers (144 males, 46 females, 21.6 ± 4.0 years; 24.7 ± 2.9 kg/m^2) attending combat medic training without a history of LBP were enrolled.

Ultrasound images were obtained bilaterally at rest for the following trunk muscles: rectus abdominis, transversus abdominis (TrA), internal oblique, and external oblique, and lumbar multifidis at L4-L5. The following 4 endurance tests were assessed: supine flexor endurance test, prone extensor endurance test, and right and left horizontal side support. Independent t-tests were performed to determine if muscle thickness, muscle symmetry, or endurance times differed based on sex. Pearson product moment correlations were performed to determine the associations between height, weight, and BMI with muscle thickness values. Sex and weight were included in regression analysis to determine their contribution to the variance in trunk muscle thickness. Finally, sex, weight, and muscle thickness values were included in a regression analysis to determine their contribution to the variance in endurance times.

Muscle thickness was greater in males than females (p<0.006). However, the TrA accounted for 10% of total abdominal muscle thickness regardless of sex. Muscle symmetry ranged from 6.6%-19.8% but did not differ based on sex (p>0.34). Asymmetry was > 12% for the

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lateral abdominal muscles. Weight had a stronger correlation (r = 0.28 to 0.54) to muscle thickness as compared with height and BMI (p<0.001). Weight and sex were able to account for 23-30% of the variance in muscle thickness values while they only accounted for 6% of the variance in endurance test times. Males were able to hold the 4 endurance test postures about a minute longer than females (p<0.002). However, there was no difference in trunk extensor endurance time between the sexes (p>0.20). Relationship between endurance time with sex, height, BMI, and muscle thickness were low (r<0.20).

Muscle thickness and symmetry values were consistent with findings of prior researchers. Sex and weight were significantly associated with muscle thickness, thus their possible confounding effects should be examined and their potential role as covariates considered in future research. Sex, height, weight, BMI, and muscle thickness values were poorly related to endurance hold times.

Asymmetry of muscle thickness values was found in individuals without a history of LBP; its use as a clinical indicator or predictor for LBP requires further inquiry. This study also provides normative data for trunk muscle size and symmetry, which could be used for comparison studies in a similar population with LBP.

Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009)

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Background: Few effective strategies have been reported to prevent low back pain (LBP). The purpose of this randomized clinical trial is to determine the effects of different exercises and an education program on preventing LBP among Soldiers.

Methods: Companies of advanced individual training (AIT) Soldiers (N>2700) who are eligible and consent to the study will be randomized in clusters to receive a core stabilization exercise program (CSEP) alone, a CSEP with a psychosocial education (PSEP), a traditional exercise (TEP), or a TEP with a PSEP. Short-term outcomes will assess changes in lumbar musculature function (physical tests and ultrasound imaging) and LBP beliefs following the 12 week AIT training period. Soldiers will be followed monthly for 2 years following completion of AIT to measure the long term outcomes of LBP occurrence and severity.

Discussion: The results of this study will inform health care providers and policy makers in how to prevent LBP among Soldiers.